



Medical Review Institute of America, Inc.
America's External Review Network

DATE OF REVIEW: March 10, 2010

IRO Case #:

Description of the services in dispute:

1. Bone growth Stimulator

A description of the qualifications for each physician or other health care provider who reviewed the decision

The physician who provided this review is board certified by the American Board of Orthopaedic Surgery. This reviewer is a member of the American Academy of Orthopaedic Surgeons and the Society of Military Orthopaedic Surgeons. This reviewer has been in active practice since 2005.

Review Outcome

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

Upheld

The medical necessity cannot be established at this time for the requested bone growth stimulator.

Information provided to the IRO for review

Records from Texas Department of Insurance

Letter from 2/23/10 (1 page)

Confirmation of Receipt of a Request for A Review by an IRO (5 pages)

Request Form 2/12/10 (3 pages)

Reconsideration/Appeal of Adverse Determination 2/9/10 (2 pages)

Utilization Review Determination 1/15/10 (2 pages)

Records from

Work Status Report 2/9/10 (1 page)

Work Status Report 1/19/10 (1 page)

Reconsideration Request Additional Clinical 1/29/10 (3 pages)

Office Notes 1/19/10 (2 pages)

Office Notes 1/14/10 (1 page)

Exogen prescription Form 1/5/10 (1 page)

Letter of Medical Necessity 1/5/10 (1 page)

Office Notes 1/5/10 (1 page)

Notice of Adverse Determination (1 page)
Utilization Review Determination 12/21/09 (1 page)
Office Notes 12/15/09 (1 page)
Office Notes 12/3/09 (1 page)
Work Status Report 11/30/09 (1 page)
Work Status Report 11/17/09 (1 page)
Office Notes 11/30/09 (1 page)
Implant Record (1 page)
Work Status Report 10/8/09 (1 page)
Operative Report 11/18/09 (2 pages)
Office Notes 11/17/09 (1 page)
Utilization Review Determination 10/29/09 (1 page)
Work Status Report 9/11/09 (1 page)
Office Notes 10/8/09 (1 page)
Initial Evaluation 10/7/09 (2 pages)
Work Status Report 10/1/09 (1 page)
Designated doctor evaluation 10/1/09 (4 pages)
Work Status Report 8/27/09 (1 page)
Designated Doctor Appointment 9/16/09 (6 pages)
Office Notes 9/11/09 (1 page)
Office Notes 8/27/09 (2 pages)
Office Notes 8/14/09 (1 page)
Work Status Report 8/6/09 (1 page)
Office Notes 8/6/09 (1 page)
Work Status Report 9/24/09 (1 page)
Work Status Report 8/14/09 (1 page)
Work Status Report 6/3/09 (1 page)
Office Notes 6/24/09 (1 page)
Work Status Report 5/5/09 (1 page)
Office Notes 6/3/09 (1 page)
Office Notes 5/5/09 (2 pages)
Work Status Report 5/12/09 (1 page)
Office Notes 3/19/09 (1 page)
Office Notes 3/12/09 (1 page)
MRI Right Wrist 3/10/09 (2 pages)
Office Notes 3/6/09 (2 pages)

Patient clinical history [summary]

This is a female patient that injured her right wrist on xx/xx/xx when she fell when a rolling bag got caught and landed on her. The patient was initially placed in a splint and told she had a fracture. She then went to an orthopedic surgeon and was told that the fracture was old and that she had a TFCC injury and she was placed into a long-term arm immobilizer. An MRI of the right

wrist dated 03/10/09 showed a nondisplaced triquetral fracture. There was dorsal ulnar soft tissue swelling and no hamet hook or additional carpal fracture seen. The patient was given an ulnocarpal joint steroid injection on 08/14/09 which did not help her. The patient then underwent an MR arthrogram which demonstrated a TFCC tear. The patient subsequently underwent a shortening ulnar osteoplasty and surgical wrist arthroscopy with TFCC debridement and synovectomy on 11/18/09. The x-ray taken on 12/15/09 shows good alignment of the ulnar osteoplasty. The clinic note dated 01/05/10 states that the patient's x-rays show good alignment of the shortening osteoplasty without any obvious healing. The patient was recommended for a bone growth stimulator. The Exogen Bone Growth Stimulator prescription form states that the patient has a current smoking habit for 15 years of 1 pack per day. The clinic note dated 01/19/10 states the patient is 9 weeks out from surgery and is continuing to complain of pain at the CMC joint with pressure, especially with putting her hand flat. The x-rays taken in clinic of the right wrist show persistent osteotomy site with no obvious signs of healing. An appeal is made for a bone growth stimulator, as the patient is a smoker who is 9 weeks out from surgery with no healing of her ulnar osteoplasty.

Analysis and explanation of the decision include clinical basis, findings and conclusions used to support the decision.

There is insufficient clinical documentation submitted to determine the medical necessity for the requested bone growth stimulator. The most recent clinic note dated 01/19/10 states that the patient is 9 weeks out from surgery and the x-rays show persistent osteotomy with no obvious signs of healing. Current ODG Guidelines for bone growth stimulators state that bone growth stimulators for nonunion are recommended only when patients are at least 3 months out from the date of fracture and serial x-rays confirm that there are no progressive signs of healing and the fracture gap is 1 cm or less. The patient does have positive risk factors for nonunion including a current smoking habit; however, there were no updated clinic notes with current imaging studies revealing persistent nonunion with a documented fracture gap. The medical necessity cannot be established at this time for the requested bone growth stimulator.

A description and the source of the screening criteria or other clinical basis used to make the decision:

ODG Guidelines

Bone Growth Stimulators, Ultrasound

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)