



Notice of Independent Review Decision

DATE OF REVIEW:

02/01/2011

IRO CASE #:

DESCRIPTION OF THE SERVICE OR SERVICES IN DISPUTE

E0747-Bone Growth Stimulator

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

Doctor of Osteopathy, Board Certified Anesthesiologist, Specializing in Pain Management

REVIEW OUTCOME

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

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.

The requested E0747 - Bone Growth Stimulator is not medically necessary.

INFORMATION PROVIDED TO THE IRO FOR REVIEW

- TDI/DIVISION OF WORKERS' COMPENSATION referral form
- 01/24/11 Referral
- 01/24/11 letter from Network & Medical Operations, , with attached response regarding disputed services
- 01/20/11 Notice To LLC Of Case Assignment, DWC
- 01/20/11 Confirmation Of Receipt Of A Request For A Review, DWC
- 01/13/11 Request For A Review By An Independent Review Organization
- 01/11/11 Request for IRO Consideration letter, Patient Advocate, Orthofix
- 01/05/11 letter from Review Nurse,
- 12/16/10, 11/17/10 prescription notes, M.D.
- 12/15/10 Follow Up note, M.D.
- 11/29/10 letter from Review Nurse,
- 11/17/10, 10/20/10, 09/15/10 office notes
- 11/12/10 MRI knee (poor quality)
- 10/18/10 left knee series, Medical Center
- 09/10/10 left knee radiographs, Medical Center
- ODG Integrated Treatment/Disability Duration Guidelines – Knee & Leg (Acute & Chronic), updated 01/24/11

PATIENT CLINICAL HISTORY [SUMMARY]:

The injured individual is a male who had a piece of machinery fall on him in xx/xx. He sustained a nondisplaced left tibial plateau fracture. He was given a continuous passive motion (CPM) machine in 09/2010. There is no mention of physical therapy (PT) performed, injections, or other care. He had an x-ray in 10/2010 that showed a visible fracture line still. He had an MRI in 11/2010 that showed nonunion and the attending physician (AP) suggested a bone stimulator. His consult of xx/xx indicated he had no past medical history (PMH), did not smoke, and was on no medications.

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

The injured individual has an injury that is now over 90 days old but the MRI was done less than 90 days out and while it showed nonunion, a repeat study or x-ray has not been provided. In addition, no gap dimensions have been documented to indicate his nonunion is less than 1cm; there has been no cast or fixation device applied; and he has no medical issues that would place him at risk for malunion.

A DESCRIPTION AND THE SOURCE OF THE SCREENING CRITERIA OR OTHER CLINICAL BASIS USED TO MAKE THE DECISION:**ODG- OFFICIAL DISABILITY GUIDELINES & TREATMENT GUIDELINES**

Official Disability Guidelines Knee chapter: 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. (Akai, 2002) (Petrisor, 2005) (BlueCross BlueShield, 2005)

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).

(Saxena, 2005) (BlueCross BlueShield, 2007) (BlueCross BlueShield, 2008)

Criteria for use for invasive electrical bone growth stimulators:

See the Low Back Chapter.

Official Disability Guidelines back chapter: Under study. There is conflicting evidence, so case by case recommendations are necessary (some RCTs with efficacy for high risk cases). Some limited evidence exists for improving the fusion rate of spinal fusion surgery in high risk cases (e.g., revision pseudoarthrosis, instability, smoker). (Mooney, 1990) (Marks, 2000) (Akai, 2002) (Simmons, 2004)

There is no consistent medical evidence to support or refute use of these devices for improving patient outcomes; there may be a beneficial effect on fusion rates in patients at "high risk", but this has not been convincingly demonstrated. (Resnick, 2005) Also see Fusion for limited number of indications for spinal fusion surgery. See Knee & Leg Chapter for more information on use of Bone-growth stimulators for long bone fractures, where they are recommended for certain conditions.

Criteria for use for invasive or non-invasive electrical bone growth stimulators:

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to spinal fusion surgery for patients with any of the following risk factors for failed fusion: (1) One or more previous failed spinal fusion(s); (2) Grade III or worse spondylolisthesis; (3) Fusion to be performed at more than one level; (4) Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor); (5) Diabetes, Renal disease, Alcoholism; or (6) Significant osteoporosis which has been demonstrated on radiographs. (Kucharzyk, 1999) (Rogozinski, 1996) (Hodges, 2003)