Subject: **Bone Growth Stimulator***

Effective Date: **January 27, 2004**

Department(s): **Utilization Management**

Policy: The purchase of an electrical or ultrasonic bone growth stimulator is reimbursable under Plans administered by QualCare, Inc.

Objective: To ensure proper & consistent utilization.

Procedure: ONE of the following must be present for consideration of coverage of a bone growth stimulator in either A or B below:

A. Electrical bone growth stimulator (E0747 – 0749)

1. Non-union of a long bone or carpal/tarsal bone fracture at least three months after the fracture occurred (long bones include clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal or metatarsal bone).
2. Congenital pseudoarthrosis with no evidence of progression of healing for at least three months despite appropriate management
3. Delayed union of fracture or failed arthrodesis at high risk site, including but not limited to scaphoid (carpal navicular) or open or segmental tibial fracture
4. Adjunct to surgical lumbar spinal fusion of two or more spinal segments
5. Any other condition in which, on medical review, it is determined that electrical stimulation is likely

to avoid the need for open reduction and/or bone graft

6. Failed lumbar spinal fusion at least six months after the original surgery, or high risk of fusion failure when ONE or more of the following criteria are met:
    a) One or more failed fusions
    b) Grade II or worse spondylolisthesis
    c) Other risk factors for fusion failure, including but not necessarily limited to:
        i. Morbid obesity
        ii. Degenerative osteoarthritis
        iii. Severe spondylolisthesis
        iv. Current smoking
        v. Prior fusion surgery
        vi. Prior disc surgery
        vii. Gross instability

Electrical bone growth stimulators are **not covered** for the treatment of fresh fractures, stress fractures, fractures with malalignment, synovial pseudoarthrosis, when the bone gap is greater than 1 cm or to enhance the healing of fractures at high risk for delayed healing or non-union.

B. Ultrasound Bone Growth stimulator(HCPCS-E0760)

1. Fresh fracture, fusion, or delayed union of open or segmental fracture of tibial shaft
2. Fresh fracture, fusion, or delayed union of scaphoid (carpal navicular) or distal radius
3. Fresh Jones fracture (5^{th} metatarsal base)
4. Non-union of bones other than the skull and vertebrae: for a fracture at least three months after the fracture occurred documented by at least two sets of imaging studies a minimum of 90 days apart.
5. Congenital pseudoarthrosis with no evidence of progression of healing for at least three months despite appropriate management

6. Closed fractures with a comorbidity that increases the risk of delayed healing or non-union, such as smoking, diabetes, renal disease.
7. Non-union of a stress fracture after a minimum of 90 days of non-surgical management documented by at least two sets of imaging studies a minimum of 90 days apart.

Ultrasound bone growth stimulators are **not covered** in the acute treatment of a fracture requiring open reduction and internal fixation(ORIF), fresh fractures not listed in section B above , for
a bone gap greater than 1 cm, or acute stress fractures.

References:

Al-Jabri T, Tan JYQ, Tong GY, Shenoy R, Kayani B, Parratt T, Khan T: The role of electrical stimulation in the
management of avascular necrosis of the femoral head in adults: a systematic review. BMC Musculoskelet
Disord 2017;18:319.

Buza JA 3rd, Einhorn T. Bone healing in 2016. Clin Cases Miner Bone Metab. 2016;13(2):101-105(May-Aug)

Ebrahim S, Mollon B, Bance S, Busse JW, Bhandari M. Low-intensity pulsed ultrasonography versus electrical stimulation for fracture healing: a systematic review and network meta-analysis. Can J Surg. 2014 ;57(3):E105-18.(Jun).

Hannemann PF, Mommers EH, Schots JP, Brink PR, Poeze M. The effects of low-intensity pulsed ultrasound and pulsed electromagnetic fields bone growth stimulation in acute fractures: a systematic review and meta-analysis of randomized controlled trials. Arch Orthop Trauma Surg. 2014;134(8):1093-106(Aug)

Griffin XL, Parsons N, Costa ML, Metcalfe D. Ultrasound and shockwave therapy for acute fractures in adults. Cochrane Database Syst Rev. 2014;6:CD008579.(Jun)

Shi HF, Xiong J, Chen YX et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. BMC Musculoskelet Disord. 2013; 14:35.(Jan)

Assiotis A1, Sachinis NP, Chalidis BE. Pulsed electromagnetic fields for the treatment of tibial delayed unions and nonunions. A prospective clinical study and review of the literature. J Orthop Surg Res. 2012 8;7:24(Jun)

Hannemann PF, Göttgens KW, van Wely BJ, et al. The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial. J Bone Joint Surg Br. 2012; 94(10):1403-1408(Oct)

Adie S, Harris IA, Naylor JM, Bergman G, Norling T, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. J Bone Joint Surg Am. 2011; 93(17):1569-1576.(Sep)

Beck, BR, Matheson, GO, Bergman, G, et al. Do capacitively coupled electric fields acceleratetibial stress fracture healing? A randomized controlled trial. Am J Sports Med. 2008;36:545-53.(Mar)

Busse JW, Kaur J, Mollon B, Bhandari M, et al. Low intensity pulsed ultrasonography for fractures: a systematic review of randomized controlled trials. BMJ. 2009; 338: b 351. doi:10.1136/bmj.b351.

American Academy of Orthopaedic Surgeons. Nonunions.
Available at: http://orthoinfo.aaos.org/topic.cfm?topic=A00374 Accessed 04/30/09

Mollon B, da Silva V, Busse JW, *et al*. Electrical stimulation for long-bone fracture-healing: A meta-analysis of randomized controlled trials. *J Bone Joint Surg Am* 2008;90(11):2322-2330 (Nov)

Foley KT, Mroz TE, Arnold PM, *et al*. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J* 2008;8(3):436-442 (May-Jun)

Walker NA, Denegar CR, Preische J. Low-intensity pulsed ultrasound and pulsed electromagnetic field in the treatment of tibial fractures: A systematic review. *J Athl Train* 2007;42(4):530-535 (Oct-Dec)

Center for Medicare & Medicaid Services (CMS). Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing. CMS Manual System Pub 100-04 Medicare Claims Processing. Transmittal 816 January 20, 2006. available at http://www.cms.hhs.gov/Transmittals/ Downloads/R816CP.pdf. accessed 10/30/07

American Academy of Orthopedic Surgeons. Nonunions. available at http://orthoinfo.aaos.org/topic.cfm?topic=A00374&return_link=0 accessed 10/30/07

Zura RD, Sasser B, Sabesan V, *et al*. A survey of orthopaedic traumatologists concerning the use of bone growth stimulators. *J Orthop Adv* 2007;16(1):1-4 (Spring)

Ricardo M. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. *Int Orthop* 2006;30(2):123-127 (Apr)

Mandracchia VJ, Nickles WA, Mandi DM, *et al*. Treatment of nonunited hindfoot fusions. *Clin Podiatr Med Surg* 2004;21(3):417-439 (Jul)

Nelson FR, Brighton CT, Ryaby J, *et al*. Use of physical forces in bone healing. *J Am Acad Orthop Surg* 2003;11(5):344-354 (Sep)

LaVelle DG. Delayed Union and Nonunion of Fractures. Ch 56 in Canale ST, ed. Campbell's Operative Orthopaedics, 10th Ed. St. Louis. Mosby. 2003. p 3125 *ff*.

Eck JC, Hodges SD, Humphreys SC. Techniques for stimulating spinal fusion: efficacy of electricity, ultrasound, and biologic factors in achieving fusion. *Am J Orthop* 2001;30(7):535-541 (Jul)

Hannouche D, Petite H, Sedel L. Current trends in the enhancement of fracture healing. *J Bone Joint Burg Br*2001;83(2):157-164 (Mar)

Centers for Medicare & Medicaid Services. NCD for Osteogenic Stimulation. Medicare Coverage Database Manual Section 35-48 2001 (January 1)

Ryaby JT. Clinical effects of electromagnetic and electric fields on fracture healing. *Clin Orthop* 1998;355(suppl):S205-215 (Oct)

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*Consistent with Summary Plan Description (SPD). When there is discordance between this policy and the SPD, the provisions of the SPD prevail.