

Origination Date: 1/07	Revision Date(s): 1/08, 1/09, 2/11
Developed By: Medical Criteria Committee	



Approved: Neal Mills MD, MBA **Date:** 3/15/2011

Description:

Bone growth stimulation is a technique of promoting bone growth in difficult to heal fractures. Two types of bone growth stimulators currently exist: electrical and ultrasonic.

An electric bone growth stimulator uses electric current to promote bone healing. Non-invasive, semi-invasive, and invasive methods of electrical bone growth stimulation are available. Non-invasive uses an external power supply and externally applied coils that produce direct current or pulsed electromagnetic fields to generate a weak electrical current in the underlying tissue. Semi-invasive, also called percutaneous bone growth stimulation uses an external power supply and electrodes that are inserted through the skin and into the bone where the growth is desired. Invasive bone growth stimulators require surgical implantation of a current generator into a subcutaneous or intramuscular space and an electrode that is implanted into the bone fragments at the fusion site. A second surgical procedure is required to remove the power source after treatment is complete.

Ultrasonic fracture healing is a noninvasive treatment that utilizes low intensity, pulsed ultrasound delivered through a skin surface transducer placed directly over the fracture site. It is used to accelerate healing of fresh fractures and fracture nonunions of sites that are difficult to heal because of poor vascular supply. It is frequently used in conjunction with orthopedic treatments such as a cast or splint. The device is portable and can be used by the patient at home in daily 20 minute sessions. The Sonic Accelerated Fracture Healing System (SAFHS) is a type of ultrasound bone growth stimulator.

Criteria:

I. Electric Bone Growth Stimulators

- A. Non-invasive electrical bone growth stimulators will be covered to plan limitations for skeletally mature individuals when **one** of the following criteria are met:
 - 1. Failed joint fusion following arthrodesis. Failed joint fusion is defined as a joint fusion which has not healed at a minimum of 6 (3Cigna) months after arthrodesis, as evidenced by serial x-rays over a course of 3 months; or
 - 2. Failed spinal fusion. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 (3 Cigna) months after the original surgery, as evidenced by serial x-rays over a course of 3 months; or
 - 3. Congenital pseudoarthroses; or
 - 4. Fracture nonunions that meet **all** of the following criteria:
 - a. Location in the appendicular skeleton (i.e. the bones of the shoulder girdle, upper and lower extremities); and
 - b. At least 3 months have passed since the date of fracture; and
 - c. Serial radiographs have confirmed that no progressive signs of healing have occurred; and
 - d. The fracture gap is ≤ 1 cm; and
 - e. The patient can be adequately immobilized and is likely to comply with non-weight bearing.

- B. Invasive or non-invasive electrical bone growth stimulators will be covered to plan limitations for skeletally mature individuals as an adjunct to spinal fusion surgery when **one** of the following risk factors for failed fusion are present:
 - 1. One or more previous failed spinal fusions
 - 2. Grade III or worse spondylolisthesis

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3. Fusion to be performed at more than one level
 4. Patient is currently a smoker
 5. Patient has diabetes
 6. Patient has renal disease
 7. Patient has a history of alcoholism
 8. Patient has significant osteoporosis which has been demonstrated on x-rays
- C. Invasive electrical bone growth stimulation will be covered to plan limitations for skeletally mature individuals when used as an adjunct to surgical treatment of non-union of a major long bone fracture.
- D. Electrical bone growth stimulation is considered investigational when used in the treatment of the following:
1. Fresh fractures
 2. Delayed unions

II. Ultrasonic Bone Growth Stimulators

Ultrasonic bone growth stimulators will be covered to plan limitations for skeletally mature individuals with any of the following conditions:

A. Fresh Fractures

Most fresh fractures heal with the use of standard fracture care such as closed reduction and cast immobilization. Ultrasonic bone growth stimulators may be indicated for the treatment of fresh, fractures in skeletally mature adults when one of the following risk factors for delayed fracture healing or nonunion are present:

1. Diabetes
2. Osteoporosis
3. Steroid therapy
4. Current smoker
5. History of alcohol abuse
6. Fracture of the tibia that is closed or grade I open or segmental
7. Jone's fracture
8. Fracture of metatarsal
9. Fracture of navicular bone in the wrist (also called scaphoid)
10. Fractures associated with extensive soft tissue or vascular damage

B. Nonunions

Ultrasonic bone growth stimulators may be indicated for the treatment of fracture nonunions, *excluding* the skull and vertebrae, when all of the following criteria are met:

1. At least 3 months have elapsed since the date of fracture and the initiation of conventional fracture treatments; and
2. Serial x-rays have confirmed that no progressive signs of healing have occurred; and
3. The fracture gap is ≤ 1 centimeter; and
4. The patient can be adequately immobilized and is determined to be otherwise appropriate for therapy and will adhere to the treatment

C. Other applications of ultrasound bone growth stimulators are considered investigational. These include but are not limited to:

1. Delayed unions
2. Pathological fractures due to malignancy
3. Closed fresh fractures with open reduction
4. Axial skeletal (skull and vertebrae) fractures, failed fusions, or nonunions

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Information to be Submitted with Pre-Authorization Request:

- Chart notes from the treating physician showing documentation of original injury and current medical status
- Treatment history
- X-ray reports

Applicable CPT/HCPC:

Note: This list may not be all-inclusive

20974: Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975: Electrical stimulation to aid bone healing; invasive (operative)
20979: Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0747: Osteogenesis stimulator; electrical, noninvasive, other than spinal applications
E0748: Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749: Osteogenesis stimulator, electrical, surgically implanted
E0760: Osteogenesis stimulator, low intensity ultrasound, noninvasive

References:

- Busse JW, Kaur J, Mollon B, Bhandari M, Tornetta P 3rd, Schünemann HJ, Guyatt GH. Low intensity pulsed ultrasonography for fractures: systematic review of randomized controlled trials. *BMJ*. 2009 Feb;338:b351.
- Centers for Medicare & Medicaid Services. National Coverage Determinations for Osteogenic Stimulation (150.2) January 1, 2001.
- EBI Biomet Medical. Implantable fusion stimulators. Accessed on February 15, 2011 at: <http://www.biomet.com/spine/products.cfm?pdid=3&majcid=11&prodid=135>
- Exogen Bone Healing System. Copyright 2006 Smith & Nephew. Accessed February 15, 2011 at: http://global.smith-nephew.com/us/ABOUT_EXOGEN_7227_ABOUT_EXOGEN_7347.htm
- Kristiansen T, Ryaby J, McCabe J, Frey J, Roe L. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo controlled study. *J Bone Joint Surg*. 1997 Jul;79(7):961-73.
- Malizos KN, Hantes ME, Protopappas V, Papachristos A. Low-intensity pulsed ultrasound for bone healing: an overview. *Injury*. 2006 Apr;37 Suppl 1:S56-62.
- Rubin C, Bolander M, Ryaby J, Hadjiargyrou M. The use of low-intensity ultrasound to accelerate the healing of fractures. *The Journal of Bone & Joint Surgery*. 2001 Feb;86-A(2):259-270.
- Sherman, J. External bone growth stimulators for spine fusion. Accessed February 15, 2011 at: <http://www.spine-health.com/topics/surg/stimulator/stim03.html>
- Sherman, J. Internal bone growth stimulators for spine fusion. Accessed February 15, 2011 at: <http://www.spine-health.com/topics/surg/stimulator/stim02.html>.
- Raasch WG, Hergan DJ. Treatment of stress fractures: The fundamentals. *Clin Sports Med*. 2006 Jan;25(1):29-36.,
- U.S. Food and Drug Administration. Center for Devices and Radiological Health (CDRH). Exogen 2000 or Sonic Accelerated Fracture Healing System. Summary of safety and effectiveness. Accessed on February 15, 2011 at: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfTopic/pma/pma.cfm?num=P900009S006>
- Physician Advisors

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