MEDICAL POLICY

MEDICAL POLICY DETAILS	
Medical Policy Title	**BONE GROWTH STIMULATORS FOR THE APPENDICULAR SKELETON**
Policy Number	**1.01.53**
Category	**Equipment/Supplies**
Effective Date	**10/18/01**
Revised Date	**10/18/01, 02/21/02, 01/16/03, 02/19/04, 02/24/05, 02/23/06, 12/07/06, 10/24/07, 08/28/08, 10/28/09, 04/28/11, 04/26/12, 06/28/12, 04/25/13, 04/24/14, 04/23/15, 06/22/16, 06/22/17, 04/26/18, 02/28/19, 2/27/20**
Product Disclaimer	• *If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.* • *If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.*

POLICY STATEMENT

I. **ELECTRICAL BONE GROWTH STIMULATOR**

A. Based upon our criteria and assessment of the peer-reviewed literature, electrical bone growth stimulation has not been demonstrated to improve patient outcomes in the applications of fresh fractures, stress fractures, *delayed unions***,** or fresh bunionectomies and, therefore, is considered **investigational**.

B. Based upon our criteria and review of the peer reviewed literature *non-invasive* electrical bone growth stimulation for the treatment of *non-union* secondary to trauma has been medically proven to be effective and therefore, is conisidered **medically appropriate** for the following indications:

1. The treatment is for-*non-union* secondary to trauma of the bones of the appendicular skeleton, including the humerus, ulna, radius, carpals, metacarpals, femur, tibia, fibula, tarsals, metatarsals, phalanges, scapula, clavicle, pelvis and patella. Coverage will only be available to patients who meet ALL of the following criteria:
   a. Three months or more have elapsed since injury or initial treatment;
   b. Serial radiographs of the preceding three-month period have confirmed that no progressive signs of healing have occurred or that the injury is greater than six months, shows no progressive signs of healing, and has not been actively treated;
   c. The fracture gap is one centimeter or less; and
   d. The patient can be adequately immobilized and, when appropriate, is likely to comply with non-weight bearing.
2. The treatment is for infantile non-union;
3. The treatment is for failed joint fusion secondary to failed arthrodesis of the ankle or knee; and
4. The treatment is non-surgical salvage for pseudoarthrosis (minimum nine months after last lumbar spinal fusion surgery).

C. Contraindications to the use of an electrical bone growth stimulation include:

1. Fracture gaps greater than one centimeter; and
2. Patients with a demand-type pacemaker or an implantable cardioverter defibrillator.

II. **ULTRASONIC BONE GROWTH STIMULATOR –**

A. Based upon our criteria and assessment of the peer-reviewed literature, ultrasound accelerated fracture-healing systems have been proven to be medically effective when used to treat *non-union* fractures (excluding fractures of

the skull or vertebrae and tumor-related fractures) and are therefore, considered **medically appropriate** when all of the following criteria are met:

1. At least three months have elapsed since injury;
2. Nonunion of the fracture is documented by a minimum of two sets of radiographs obtained prior to starting treatment with the ultrasonic (US) device, separated by a minimum of 90 days, each including multiple views of the fracture site, and with written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs;
3. The fracture gap is one cm or less; and
4. The patient can be adequately immobilized and is of an age where likely to comply with non-weightbearing.

B. Based upon our criteria and review of the peer-reviewed literature ultrasound accelerated fracture healing systems do not significantly improve patient outcomes and are therefore, considered **not medically necessary** for the following indications:

1. To accelerate healing of fresh, closed, posteriorly displaced distal radius fractures,
2. To accelerate healing of fresh, closed or Grade 1 tibial diaphysis fractures;
3. To accelerate fresh fractures, fusions, or delayed unions of the scaphoid (carpal navicular).
4. To treat delayed union of fractures;
5. To treat congenital pseudoarthrosis;
6. To treat Charcot arthropathy; (except that treatment of fractures related to Charcot arthropathy using ultrasonic bone growth stimulators are considered medically necessary when all of the criteria listed in IIA are met); and
7. To treat Osteogenesis Imperfecta.

Refer to Corporate Medical Policy #7.01.40 Bone Growth Stimulators; Invasive and Noninvasive Electrical Stimulation of the Spine.

Refer to Corporate Medical Policy # 2.01.31 Extracorporeal Shock Wave Therapy (ESWT) for Musculoskeletal Conditions and Soft Tissue Wounds.

POLICY GUIDELINES

I. Prior authorization is contract dependent. Please refer to your Customer (Member/Provider) Services Department for contract information.

II. Durable medical equipment rider/coverage is required.

III. Ultrasound accelerated healing devices are not to be used in conjunction with any other noninvasive osteogenic stimulation devices.

IV. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION

I. **Electrical bone growth stimulators** are used to induce the growth of bones in cases of delayed union or non-union of fractures. Two methods of electrical bone growth stimulation are available:

A. **Non-invasive** stimulators use an external power supply and externally applied coils that produce an electrical current to the fracture site via Pulsed Electromagnetic Fields (PEMFs), Combined Electromagnetic Field (CEMF) technology, or capacitive coupling to stimulate bone growth.

B. **Invasive stimulators** use a current generator that is surgically implanted in an intramuscular subcutaneous space and connected to an electrode that is implanted within the bone fragments that are hoped to be fused. The power source is removed in a second surgical procedure once it has discharged.

II. **Ultrasonic Accelerated Fracture**, or **Sonic Accelerated Fracture Healing System** (SAFHS), is a non-invasive device that uses low intensity, pulsed, ultrasound therapy to stimulate and accelerate fracture healing time. The device consists of two main components: a signal generator about the size of a laptop computer and a small, square transducer connected to the generator by cable. The transducer is applied to the skin over the fracture site using a gel to facilitate transmission of the ultrasound signal.

Delayed unions are defined by using clinical and radiographic findings suggesting an un-united fracture where the possibility of healing exists. Healing has not advanced at the "average" rate for the location and type of fracture.

Non-unions are defined by radiographic findings with clinical mobility of the bone fragments, where bone healing has ceased, and more than three months since the fracture occurred.

Delayed union differs from non-union in that, with the former, there are no indications that union will fail, while with the latter, there are no longer any visible signs that union will occur.

RATIONALE

The FDA has given premarket approval for the Biomet® EBI Bone Healing System, the Orthologic Bone Growth Stimulator, Biomet®SpinalPak, Spinal-Stim Lite, Orthofix® Physio-Stim Life, OrthoPak® Bone Growth Stimulator Systems, and SpinaLogic external stimulators and the Zimmer Biomet® Orthogen/ Osteogen, Zimmer Biomet® Direct Current Bone Growth Stimulator, and SpF® implanted spinal fusion stimulators.

There is sufficient evidence reported in the peer-reviewed literature to conclude that external electrical stimulation improves outcomes for non-union of fractures, for infantile non-union, for failed joint fusion, and for non-surgical salvage for pseudoarthrosis. Non-invasive and invasive electrical bone stimulation improves outcomes when used as an adjunct to spinal fusion surgery for patients at high risk for pseudoarthrosis. Improved outcomes have been achieved outside the investigational setting. A randomized controlled trial to determine whether interferential current could significantly reduce healing time in new fractures of the tibia or prevent non-union found no significant difference in time to union compared to placebo. A randomized controlled trial to determine whether interferential current would accelerate tibial stress fracture healing found no difference in time to healing between treatment and placebo groups. Greater device use and less weightbearing loading enhanced the effectiveness of the active device. A 2002 meta-analysis of trials of the effect of electrical stimulation on musculoskeletal systems included four studies of fresh fractures, all of them failing to provide evidence of efficacy.

The FDA approved the BioniCare® Stimulator Model BIO-1000™ in 2003 for use as an adjunctive therapy in reducing the level of pain and symptoms associated with osteoarthritis of the knee. The BioniCare® device is purported to stimulate chondrogenesis, however no studies have been performed in humans to evaluate whether chondrogenesis occurs with use of this device. No studies of the use of electrical bone growth stimulators in bunionectomies were identified.

FDA premarket approval was granted to the Exogen 2000® Sonic Accelerated Fracture Healing System (SAFHS®) in 1994 for treatment of fresh Colles fractures and open tibial diaphysis fractures when managed by closed reduction and casting and approval was expanded to non-unions in 2000. Data presented to the FDA as part of the approval process for the SAFHS® device demonstrated that in64 of 74 cases, non-unions (mean fracture age nearly three years) were healed with use of low-intensity ultrasound. Patients receiving drugs that alter bone metabolism were excluded from studies of the device. Two studies of ultrasound after intramedullary nailing and fixation with absorbable screws showed no benefit from ultrasound. Most fresh fractures heal following standard care, such as closed reduction and casting. The United Kingdom’s National Institute for Health and Clinical Excellence (NICE) updated its guidance on low-intensity pulsed ultrasound for the treatment of nonunion and delayed fracture healing in 2013. NICE reached the following conclusions: Clinical evidence shows a high rate of fracture healing which supports the use of the EXOGEN ultrasound bone healing system to treat long-bone fractures with nonunion (failure to heal after nine months). In addition, the EXOGEN ultrasound bone healing system to treat long-bone fractures with nonunion is associated with an estimated cost saving when compared with current management, through the avoidance of surgery. There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long-bone fractures with delayed healing (no radiological evidence of healing after approximately three months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between three and nine months after fracture, and

about whether or not surgery would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management.

Small randomized controlled trials suggest that ultrasound may accelerate healing of fresh fractures and promote healing in subgroups at risk for non-union. Larger trials are needed to confirm this. No studies were identified that included children less than 17 years old. The mechanism for the effect of ultrasound on bone healing is not fully understood.

The American Academy of Orthopedic Surgeons (AAOS) publishes information on nonunions, which occur when a broken bone fails to heal and a "delayed union", which is when a fracture takes longer than usual to heal. Some broken bones do not heal even when they get the best surgical or nonsurgical treatment because of inadequate stability, a limited blood supply, or lack of good nutrition to promote healing. Some bones can be expected to heal with minimal treatment due to inherent stability and excellent blood supply (toe bones). Other bones may not heal as quickly due to a limited blood supply (femoral head and neck, small wrist bone (scaphoid). Bones with moderate blood supply (tibia) may not heal quickly because the skin and muscle over the bone was damaged and the external blood supply was impaired. In addition, certain risk factors make it more likely that a bone will fail to heal. These risk factors include tobacco or nicotine use in any form, older age, severe anemia, diabetes, hypothyroidism, infection, certain medications, and low vitamin D level.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*

CPT Codes

Code	Description
20974	Electrical stimulation to aid bone healing; non-invasive (non-operative)
20975	invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes

Code	Description
E0747	Osteogenesis stimulator, electrical, non-invasive; other than spinal applications
E0748	spinal applications
E0749	surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive

ICD10 Codes

Code	Description
M80.00xS	Age-related osteoporosis with current pathological fracture, unspecified site, sequela
M80.021A-M80.879A	Osteoporosis with current pathological fracture, initial encounter for fracture (code range)
M84.30xS	Stress fracture, unspecified site, sequela
M84.38xS	Stress fracture, other site, sequela

Code	Description
M84.40xS	Pathological fracture, unspecified site, sequela
M84.421A-M84.48xA	Pathological fracture, initial encounter for fracture (code range)
M84.68xS	Pathological fracture in other disease, other site, sequela
Q68.8	Other specified congenital musculoskeletal deformities
Q71.61-Q71.63	Lobster-claw right hand, left hand, bilateral (code range)
Q74.0-Q74.9	Other congenital malformations of limb(s) (code range)
Q87.0	Congenital malformation syndromes predominantly affecting facial appearance
S42.201A-S42.9XB	Fracture of shoulder and upper arm, initial encounter for closed or open fracture (code range)
S49.001A-S49.199A	Other and unspecified injuries of shoulder and upper arm, initial encounter for closed fracture (code range)
S52.001A-S52.92XR	Fracture of ulna and forearm, initial encounter for closed or open fracture, initial encounter (code range)
S59.101A-S59.199A	Other and unspecified injuries of upper end of radius, initial encounter for closed fracture (code range)
S72.001A-S72.499C	Fracture of femur, initial encounter for closed fracture, initial encounter for open fracture type I or II, initial encounter for open fracture type IIIA, IIIB, or IIIC (code range)
S79.001A-S79.199A	Other and unspecified injuries of hip and thigh, initial encounter for closed fracture, (code range)
S82.101A-S82.866C	Fracture of lower leg, including ankle, initial encounter for closed fracture, initial encounter for open fracture type I or II, initial encounter for open fracture type IIIA, IIIB, or IIIC (code range)
S89.001A-S89.299A	Other and unspecified injuries of lower leg, initial encounter for closed fracture (code range)
S92.301A-S92.356B	Fracture of unspecified metatarsal bone(s) and great toe, initial encounter for closed or open fracture, (code range)

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*Key Article

KEY WORDS

Bone Growth Stimulator, Osteogenic Stimulator, SAFHS, Ultrasonic Bone Growth Stimulator, US.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Osteogenic Stimulators. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&bc=BAABAAAAAAAA&