MEDICAL POLICY

Excellus

SUBJECT: BONE GROWTH STIMULATORS	EFFECTIVE DATE: 11/19/99 REVISED DATE: 11/02/00, 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
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- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

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 **medically appropriate** for the following indications:

1. The treatment 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. In order for coverage to be available, patients must meet all of the following criteria:
   a. Greater than or equal to 3 months have elapsed since injury or initial treatment;
   b. Serial radiographs of the preceding 3 month period have confirmed that no progressive signs of healing have occurred or unless the injury is greater than 6 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 of infantile non-union; or
3. The treatment of failed joint fusion secondary to failed arthrodesis of the ankle or knee; or
4. As a non-surgical salvage for pseudoarthrosis (minimum nine months after last lumbar spinal fusion surgery).

C. Invasive and non-invasive methods of electrical bone growth stimulation are considered **medically appropriate** when used as an adjunct to lumbar spinal fusion surgery for patients at high risk for pseudoarthrosis, including but not limited to, those with the following conditions:

1. One or more previous failed spinal fusions;
2. Grade III or worse spondylolisthesis;
3. Fusion to be performed at more than one level; or
4. Disease processes or condition that interferes with the healing process (e.g., diabetes, renal disease, smoking, alcoholism, and steroid use).

D. Invasive and noninvasive electrical stimulation are considered **investigational** as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

E. 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 **medically appropriate** when all of the following criteria are met:
   1. At least 3 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 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 **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; or
   5. Treatment of congenital pseudoarthrosis; or
   6. Treatment of Charcot arthropathy; treatment of fractures related to Charcot arthropathy using ultrasonic bone growth stimulators may be considered **medically necessary** when all of the criteria listed in IIA are met; or
   7. Treatment of Osteogenesis Imperfecta.

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 (CMF) 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 ununited 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 as radiographic findings with clinical mobility of the bone fragments and where bone healing has ceased and there has been more than 3 months since the time of the fracture.

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

Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months.

Refer to Corporate Medical Policy # 2.01.31 regarding Extracorporeal Shock Wave Therapy

RATIONALE:

The FDA has given premarket approval for the EBI Bone Healing System, the Orthologic Bone Growth Stimulator, SpinalPak, Spinal-Stim Lite, Physio-Stim Life, OrthoPak, and SpinaLogic external stimulators and the Orthogen/ Osteogen, Zimmer 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, 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 if 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 if 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 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 expanded to non-unions in 2000. Data presented to the FDA as part of the approval process for the SAFHS® device demonstrated that 64 of 74 cases of non-union (mean fracture age nearly 3 years) were healed with use of low-intensity ultrasound. Patients receiving drugs which 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 their 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 9 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 avoiding 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 3 months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 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 affect of ultrasound on bone healing is not fully understood.

Foley et al published results of the investigational device exemption study of pulsed electromagnetic field (PEMF) stimulation (Cervical-Stim device from Orthofix) as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants. A total of 323 patients were randomized, 163 to PEMF and 160 to no stimulation. All patients were active smokers (more than one pack of cigarettes per day, 159 patients) or were undergoing multilevel ACDF (192 patients). The patients in the treatment group wore the Cervical-Stim device for 4 hours per day for 3 months starting 1 week after surgery. Efficacy was measured by radiographic analysis at 1, 2, 3, 6, and 12 months. Fusion rates for the 240 evaluable patients at 6 months were 83.6% for the PEMF group and 68.6% for the control group (p=.0065). By intent-to-treat analysis, assuming that nonevaluable patients did not have fusion, PEMF and control groups fusion rates were 65.6% and 56.3%, respectively (p=.0835). Of 245 patients available for follow-up at 12 months, fusion was achieved in116 of 125 PEMF patients and 104 of 120 control patients (p=.1129). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not included in the paper. The large number of dropouts, non-significant difference in fusion rates by intent-to-treat analysis, and lack of data on functional outcomes (e.g., pain, return to usual activity) limit interpretation of these study results. Thus, this technique is considered investigational for the cervical spine.

CODES:	Number	Description

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:	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:	E0747	Osteogenesis stimulator, electrical, non-invasive; other than spinal applications
	E0748	spinal applications
	E0749	surgically implanted
	E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive
ICD9:	724.6	Spinal fusion
	733.11	Pathologic fracture of humerus

	733.12	Pathologic fracture of distal radius and ulna
	733.14	Pathologic fracture of neck of femur
	733.15	Pathologic fracture of other specified part of femur
	733.16	Pathologic fracture of tibia or fibula
	733.81	Malunion of fracture
	733.82	Nonunion of fracture
	755.50- 755.60	Congenital pseudoarthrosis
	812.00-812.59	Closed or open fracture of humerus (code range)
	813.00-813.30	Closed or open fracture of radius and ulna (code range)
	813.40-813.93	Closed or open fracture of forearm (code range)
	820.00-820.19	Closed or open fracture of unspecified intracapsular section of femur (code range)
	820.20-820.32	Pertrochanteric fracture, closed or open (code range)
	820.8	Fracture of unspecified part of neck of femur, closed
	820.9	Fracture of unspecified part of neck of femur, open
	821.00-821.39	Closed or open fracture of femur (code range)
	823.00-823.92	Closed or open fracture of tibia and fibula (code range)
	825.25-825.35	Closed or open fracture of metatarsal bone(s) (code range)
	905.5	Failed bone fusion
ICD10:	M43.27-M43.28	Fusion of spine, lumbosacral, sacral and sacrococcygeal region (code range)
	M53.2x7-M53.2x8	Spinal instabilities, lumbosacral, sacral and sacrococcygeal region (code range)
	M53.3	Sacrococcygeal disorders, not elsewhere classified
	M53.86-M53.88	Other specified dorsopathies, lumbosacral, sacral and sacrococcygeal region (code range)
	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
	M84.40xS	Pathological fracture, unspecified site, sequela
	M84.421A-M84.673A	Disorder of continuity of bone, 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	Lobster-claw right hand

Q71.63	Lobster-claw hand, bilateral
Q74.0-Q74.9	Other congenital malformations of limb(s) (code range)
Q87.0	Congenital malformation syndromes predominantly affecting facial appearance
S42.201A-S42.92B	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-S52.92C	Fracture of forearm, initial encounter for closed or open fracture, initial encounter for open fracture type IIIA, IIIB, or IIIC (code range)
S59.101A-S59.199A	Other and unspecified injuries of elbow and forearm, 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&