MEDICAL POLICY

POLICY TITLE	OSTEOGENIC STIMULATORS
POLICY NUMBER	MP-1.024

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I. POLICY

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as treatment of fracture nonunions, or congenital pseudoarthroses in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities). The diagnosis of fracture nonunion must meet ALL of the following criteria:

- At least 3 months have passed since the date of fracture or date of surgery;
- Serial radiographs have confirmed that no progressive signs of healing have occurred; and
- The patient can be immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

Investigational applications of electrical bone growth stimulation include, but are not limited to, immediate post-surgical treatment after appendicular skeletal surgery, stress fractures, or for the treatment of fresh fractures, or delayed union. (See Policy Guidelines for definition of delayed union. .

Implantable and semi-invasive electrical bone growth stimulators are considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

Electrical Bone Growth Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered **medically necessary** as an adjunct to lumbar spinal fusion surgery in patients at high risk for fusion failure, defined as any one of the following criteria:

- One or more previous failed spinal fusion(s);
- Grade III or worse spondylolisthesis;
- Fusion to be performed at more than one level;
- Current tobacco use;
- Diabetes;
- Renal disease;
- Alcoholism;
- Steroid use.

Noninvasive electrical bone stimulation may be considered **medically necessary** as a treatment of patients with failed lumbar spinal fusion. 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.

Semi-invasive electrical stimulation is considered **investigational** as an adjunct to lumbar fusion surgery and for failed lumbar fusion. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Invasive, semi-invasive, and noninvasive electrical stimulation are considered **investigational** as an adjunct to cervical fusion surgery and for failed cervical spine fusion. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Ultrasound Accelerated Fracture Healing Device

Low-intensity ultrasound treatment may be considered **medically necessary** when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals. Candidates for ultrasound treatment are those at high risk for delayed fracture healing or nonunion. These risk factors may include either locations of fractures and patient comorbidities and include the following:

Patient comorbidities:

- Diabetes
- Steroid therapy
- Osteoporosis
- History of alcoholism

History of smoking

Fracture locations:

- Jones fracture
- Fracture of navicular bone in the wrist (also called the scaphoid)
- Fracture of metatarsal
- Fractures associated with extensive soft tissue or vascular damage

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Low-intensity ultrasound treatment may be considered **medically necessary** as a treatment of delayed union of bones, excluding the skull and vertebra. (See Policy Guidelines for definition of delayed union)

Low-intensity ultrasound treatment may be considered **medically necessary** as a treatment of fracture nonunions of bones, including nonunion of previously surgically-treated fractures, and excluding the skull and vertebra. For a fracture or post-operative site to be considered non-union, ALL of the following criteria must be met:

- At least 3 months have passed since the date of fracture or date of surgery;
- Serial radiographs have confirmed that no progressive signs of healing have occurred; and the patient can be immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

Other applications of low-intensity ultrasound treatment are **investigational**, including, but not limited to, treatment of congenital pseudoarthroses, open fractures, fresh surgically-treated closed fractures, stress fractures, arthrodesis or failed arthrodesis. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Policy Guidelines

Fresh (Acute) Fracture
A fracture is most commonly defined as "fresh" for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.

Delayed Union
Delayed union is defined as a decelerating healing process as determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

Cross-reference:
None

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II. PRODUCT VARIATIONS TOP

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

*	[N]	Capital Cares 4 Kids	[N]	Indemnity
	[N]	PPO	[N]	SpecialCare
	[N]	HMO	[N]	POS
	[Y]	SeniorBlue HMO**	[Y]	FEP PPO*
	[Y]	SeniorBlue PPO**		

Refer to the FEP Medical Policy Manual for the following policies which can be found at www.fepblue.org

MP 1.01.05 Ultrasound Accelerated Fracture Healing Device
MP 7.01.07 Electrical Grown Stimulation of the Appendicular Skeleton
MP 7.01.85. Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures.

** Refer to NHIC LCD L11501, Osteogenic Stimulators, and NCD 150.2 Osteogenic Stimulators.

III. DESCRIPTION/BACKGROUND TOP

Electrical Stimulation of the Appendicular Skeleton and Spine as an Adjunct to Spinal Fusion Procedures

In the appendicular skeleton, electrical stimulation (with either implantable electrodes or noninvasive surface stimulators) has been investigated for the treatment of delayed union, nonunion, and fresh fractures.

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the chances of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion.

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site with the production of direct current (DC) electrical stimulation. Invasive devices require surgical implantation of a

current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

- Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours per day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed onto the skin and are worn for 6–8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Patient compliance may be an issue with externally worn devices.
- Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply obviating the need for a surgical procedure to remove the generator when treatment is finished.

In the appendicular skeleton, electrical stimulation has been used primarily to treat tibial fractures, and thus this technique has often been thought of as a treatment of the long bones. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levels to facilitate motion, while short bones function to dissipate concussive forces. Short bones include those composing the carpus and tarsus. Flat bones, such as the scapula or pelvis, provide a broad surface area for attachment of muscles. Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. Each bone, depending on its physiologic function, has a different proportion of cancellous to trabecular bone. At a cellular level, however, both bone types are composed of lamellar bone and cannot be distinguished microscopically.

Nonunion

The definition of a fracture nonunion has remained controversial. The original U.S. Food and Drug Administration (FDA) labeling defined nonunion as follows: "A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months." Others have contended that 9 months represents an arbitrary cut-off point that does not reflect the complicated variables that are present in fractures, i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. Other proposed definitions of nonunion involve 3 to 6 months' time from original healing, or simply when serial x-rays fail to show any further healing.

Delayed Union
Delayed union refers to a decelerating bone healing process, as identified in serial x-rays. (In contrast, nonunion serial x-rays show no evidence of healing.) When lumped together, delayed union and nonunion are sometimes referred to as "ununited fractures."

Regulatory Status

The noninvasive OrthoPak® Bone Growth Stimulator (BioElectron) received U.S. Food and Drug Administration (FDA) premarket approval in 1984 for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all noninvasive devices) include Physio- Stim® from Orthofix Inc., first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System® from Electrobiology, Inc., which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. No distinction was made between long and short bones. The FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis.

The following implantable devices have received U.S. Food and Drug Administration (FDA) premarket approval (PMA):

- The OsteoStim® (Electro-Biology, Inc.), which may also be marketed under the trade name SPF (Biomet), has received FDA PMA.

Noninvasive bone growth stimulators that have received FDA PMA include:

- The SpinalPak® bone growth stimulator system from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a capacitive coupling system, received PMA in 1999 for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.
- The EBI Bone Healing System® from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a pulsed electromagnetic field system which was first approved in 1979 with FDA PMA and indicated for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.
- SpinaLogic Bone Growth Stimulator® (Regentek, a division of dj Orthopedics, LLC (formerly OrthoLogic, Tempe, AZ) received PMA in 1994 as a combined magnetic field portable device. This device is secured with a belt around the waist.
- Spinal-Stim Lite ® (Orthofix, Inc., Richardson, TX) received PMA in 1996 as a spinal adjunct to the Physio-Stim®. This device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.
- The Cervical-Stim® from Orthofix, Inc., Richardson, TX is a pulsed electromagnetic field system that was approved in 2004 as an adjunct to cervical fusion surgery in patients at high

risk for nonfusion. An illustration of how this particular device is worn is available at online site: http://www.orthofix.com/products/spine_cervstim.asp.

No semi-invasive electrical bone growth stimulator devices with FDA approval or clearance were identified

Ultrasound Accelerated Fracture Healing Device
Low-intensity pulsed ultrasound has been investigated as a technique to accelerate healing of fresh fractures, delayed unions, and nonunions. Ultrasound is delivered with the use of a transducer applied to the skin surface overlying the fracture site.

The majority of bone fractures heal spontaneously over the course of several months following injury. However, approximately 5%-10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services. Ultrasound may accelerate healing of fractures by stimulating new bone growth, and therefore, has been proposed as a treatment for fractures with delayed healing or at high risk for non-healing.

The current policy does not limit the use of the device to specific fracture sites. Depending on their function, bones are composed of a varying combination of cortical and trabecular bone. However, at the cellular level, the type of bone cannot be distinguished histologically. The inclusion of all bones regardless of the anatomic site is based on this histologic similarity of all bones; it is not anticipated that the efficacy of ultrasound-accelerated healing would vary according to the anatomic site and function of the bone.

The definition of a fracture nonunion has remained controversial. For electrical bone growth stimulators the U.S. Food and Drug Administration (FDA) labeling defined nonunion as follows: "A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months." Others have contended that 9 months represents an arbitrary cut-off point that does not reflect the complicated variables that are present in fractures, i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. Other proposed definitions of nonunion involve 3 to 6 months' time from original healing, or simply when serial x-rays fail to show any further healing. According to the FDA labeling for a low-intensity pulsed ultrasound device, "a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing."

Delayed union is generally considered a failure to heal between 3 and 9 months after fracture, after which the fracture site would be considered to be a nonunion. Delayed union may also be defined as a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of healing.) Together, delayed union and nonunion are sometimes referred to as "ununited fractures." To determine the status of fracture healing, it is important to include both radiographic and clinical criteria. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

Ultrasound treatment can be self-administered with one daily 20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known, but is thought to be related to a mechanical effect on cell micromotion/deformation causing an increase in stimulation of transmembrane cell adhesion molecules and upregulation of cyclooxygenase-2.

Regulatory Status

The Sonic Accelerated Fracture Healing System, SAFHS® (also referred to as Exogen 2000®) was initially cleared for marketing by the FDA in October 1994 as a treatment of fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade-I open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra.

IV. RATIONALE

TOP

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Noninvasive Bone Growth Stimulation
Nonunion
The policy regarding electrical bone stimulation as a treatment of nonunion of fractures of the appendicular skeleton is based on the labeled indications by the U.S. Food and Drug Administration (FDA). The FDA approval was based on a number of case series in which patients with nonunions, primarily of the tibia, served as their own control. These studies suggest that electrical stimulation results in subsequent unions in a significant percentage of patients. (2-6)

A 2008 systematic review of electromagnetic bone growth stimulation by Griffin and colleagues included 49 studies, 3 of which were randomized controlled trials (RCTs). (7) The 2 RCTs that included patients with nonunion and the single RCT that included patients with delayed union are described below.

A 1994 RCT by Scott and King compared capacitive coupled electric fields with sham treatment (dummy unit) in 23 patients with nonunion (fracture at least 9 months-old and without clinical or radiographic sign of progression to union within the last 3 months) of a long bone. (8) Patients with systemic bone disorders, synovial pseudoarthrosis, or fracture gap of greater than half the width of the bone were excluded. In this trial, electrodes were passed onto the skin surface through holes in the plaster cast. Twenty-one patients completed the protocol (10 treatment and 11 controls). Six months after beginning treatment, an orthopedic surgeon and a radiologist,

neither of them involved in the patients' management, examined radiographs and determined that 6 of 10 in the treatment group healed, while none of those in the control group healed (p=0.004).

In 2003, Simonis et al. compared pulsed electromagnetic field stimulation and placebo treatment for tibial shaft fractures ununited at least 1 year after fracture, no metal implant bridging the fracture gap, and no radiologic progression of healing in the 3 months before treatment. (9) All 34 patients received operative treatment with osteotomy and unilateral external fixator prior to randomization. Treatment was delivered by external coils. Patients were assessed monthly for 6 months, and clinical and radiographic assessments were conducted at 6 months. Treatment was considered a failure if union was not achieved at 6 months. In the treatment group, 89% of fractures healed compared with 50% in the control group (p=0.02). While a larger percentage of smokers in the treatment group healed than compared with those in the control group, the number of smokers in each group was not comparable, and the difference in healing rates between groups was not statistically significant. The authors conclude that the available evidence supports the use of pulsed electromagnetic field (PEMF) therapy in the treatment of nonunion of the tibia and suggest that future trials should consider which modality of electromagnetic stimulation and in which anatomical sites the treatment is most effective.

Delayed Union

Shi et al. reported a randomized sham-controlled trial that included 58 patients with delayed union of surgically-reduced long-bone fractures (femur, tibia, humerus, radius or ulna). (10) Delayed union was defined as a failure to heal after at least 16 weeks and not more than 9 months following surgical reduction and fixation of the fracture. Patients with fracture nonunion, defined as failure to heal after more than 9 months, were excluded from the study. Treatment with 8 hours of PEMF per day was stopped when no radiographic progression was observed over 3 months or when union was achieved, with union defined as no pain during joint stressing or during motion at the fracture site and callus bridging for 3 out of 4 cortices on blinded assessment. Three months of treatment resulted in a slight, but not statistically significant, improvement in the rate of union between PEMF-treated patients and controls (38.7% vs. 22.2%). The success rate was significantly greater with PEMF (77.4% vs. 48.1%) after an average of 4.8 months of treatment. The time to union was not significantly different between PEMF (4.8 months, range, 2 to 12) and sham controls (4.4 months, range 2 to 7).

In a double-blind RCT by Sharrard from 1990, PEMF stimulation was compared with a sham procedure using a dummy device in 45 patients with delayed union of the tibia. (11) Stimulators were positioned on the surface of the plaster cast. Treatment began 16 to 32 weeks after injury. Patients with fracture gaps greater than 0.5 cm after reduction, systemic disease, or taking steroids were excluded, as well as patients with marked bony atrophy or hypertrophy. Fifty-one patients were recruited, and 45 completed the protocol (20 treatment and 25 control). In the treatment group, 3 patients achieved union, 2 achieved probable union, 5 showed progression to union, and 10 showed no progress after 12 weeks. In the control group, none had united, 1 had probably united, 3 progressed toward union, and 17 showed no progress.

The policy regarding electrical stimulation of delayed unions is based on a 1992 TEC Assessment of the RCT by Sharrard, (12) which offered the following conclusions:

Sharrard reported radiographic evidence of healing at the end of the 12-week treatment period. Radiographs were rated separately by a radiologist and an orthopedic surgeon. Their inconsistent rating methods and uncertain comparability in their findings make the radiographic evidence difficult to interpret. In addition, it is uncertain whether radiographic evidence of healing after 12 weeks of treatment, an intermediate outcome, predicts health outcomes such as healing and need for subsequent surgery. In this study, there were no statistically significant differences between the active and sham groups on clinical outcomes such as movement at the fracture site, pain, and tenderness. Thus, Sharrard's health outcome data do not show that noninvasive electrical bone growth stimulation delivers an advantage over placebo.

In 2011, Griffin et al. published a Cochrane review of electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. (13) In addition to the 3 RCTs reviewed above, the systematic review included a 1984 study by Barker et al. that randomized 17 participants with tibial non-union to electromagnetic field stimulation or sham treatment. (14) Thus, 4 studies with a total of 125 participants were included for analysis. The primary outcome measure was the proportion of participants whose fractures had united at a fixed time point. For this outcome, the overall pooled effect size was small and not statistically significant (risk ratio [RR]: 1.96; 95% confidence interval [CI]: 0.86 to 4.48). Interpretation is limited due to the substantial clinical and statistical heterogeneity in the pooled analysis. In addition, there was no reduction in pain found in 2 trials, and none of the studies reported functional outcomes. The authors concluded that electromagnetic stimulation may offer some benefit in the treatment of delayed union and non-union, but the evidence is inconclusive and insufficient to inform current practice.

Section Summary. Two randomized sham-controlled trials have been identified on the treatment of delayed union with PEMF. In the Sharrard study, radiographic healing was improved at 12 weeks, but there were no statistically significant differences between groups for clinical outcomes. In the study by Shi et al., only the rate of healing at an average of 4.8 months was statistically significant, and it is not clear if this is a prespecified endpoint. The time to healing was not reduced by PEMF. Additional study is needed to permit greater certainty regarding the effect of this technology on delayed unions.

Appendicular Skeletal Surgery

A comprehensive search found 2 small randomized controlled trials on non-invasive electrical bone growth stimulation after orthopedic surgery. In 1988, Borsalino et al. reported a randomized double-blind sham-controlled trial of pulsed electromagnetic field stimulation (8 hours a day) in 32 patients who underwent femoral intertrochanteric osteotomy for osteoarthritis of the hip. (15) Radiographic measurements at 90 days revealed significant increases in the

periosteal bone callus and in trabecular bone bridging at the lateral, but not the medial cortex. The study is limited by the small sample size and the lack of clinical outcomes.

A 2004 trial randomized 64 patients (144 joints with triple arthrodesis or subtalar arthrodesis) to pulsed electromagnetic field stimulation for 12 hours a day or to an untreated control condition. (16) Patients at high risk of non-fusion (rheumatoid arthritis, diabetes mellitus, or on oral corticosteroids) were excluded from the study. Blinded radiographic evaluation found a significant decrease in the time to union (12.2 weeks for talonavicular arthrodesis vs. 17.6 weeks in the control group; 13.1 weeks for calcaneocuboid fusion vs. 17.7 weeks for the control group). Clinical outcomes were not assessed.

Fresh Fractures

A multicenter, double-blind, randomized sham-controlled trial evaluated 12 weeks of pulsed electromagnetic field stimulation for acute tibial shaft fractures. (17) The endpoints examined were secondary surgical interventions, radiographic union, and patient-reported functional outcomes. Approximately 45% of patients were compliant with treatment (>6 hours daily use), and 218 patients (84% of 259) completed the 12-month follow-up. The primary outcome, the proportion of participants requiring a secondary surgical intervention because of delayed unionor nonunion within 12 months after the injury, was similar for the 2 groups (15% active; 13% sham). Per protocol analysis comparing patients who actually received the prescribed dose of pulsed electromagnetic field stimulation versus sham treatment also showed no significant difference between groups. Secondary outcomes, which included surgical intervention for any reason (29% active; 27% sham), radiographic union at 6 months (66% active; 71% sham), and the SF-36 (Short Form) Physical Component Summary (44.9 active; 48.0 sham) and Lower Extremity Functional Scales at 12 months (48.9 active; 54.3 sham), also did not differ significantly between the groups. This sham-controlled RCT does not support a benefit for electromagnetic stimulation as an adjunctive treatment for acute tibial shaft fractures.

Another smaller (n=53) multicenter double-blind, randomized sham-controlled trial found no advantage of PEMF for the conservative treatment of fresh (<5 days from injury) scaphoid fractures. (18) Outcomes included the time to clinical and radiologic union and functional outcome.

Stress Fractures

In 2008, Beck et al. reported a well-conducted randomized controlled trial (n=44) of capacitively coupled electric fields (OrthoPak) for healing acute tibial stress fractures. (19) Patients were instructed to use the device for 15 hours each day and usage was monitored electronically. Healing was confirmed when hopping 10 cm high for 30 seconds was accomplished without pain. Although an increase in the hours of use per day was associated with a reduction in the time to healing, there was no difference in the rate of healing between treatment and placebo. Power analysis indicated that this number of patients was sufficient to detect a difference in

healing time of 3 weeks, which was considered to be a clinically significant effect. Other analyses, which suggested that electrical stimulation might be effective for the radiologic healing of more severe stress fractures, were preliminary and a beneficial effect was not observed for clinical healing.

Invasive Bone Growth Stimulation

A comprehensive search for implantable bone stimulators identified a small number of case series, all of which focused on foot and ankle arthrodesis in patients at high risk for nonunion (summarized in reference (20)). Risk factors for nonunion included smoking, diabetes mellitus, Charcot (diabetic) neuroarthropathy, steroid use, and previous nonunion. The largest case series described outcomes of foot or ankle arthrodesis in 38 high-risk patients. (21) Union was observed in 65% of cases by follow-up evaluation (n=18) or chart review (n=20). Complications were reported in 16 (40%) cases, including 6 cases of deep infection and 5 cases of painful or prominent bone stimulators necessitating stimulator removal. A multicenter retrospective review described outcomes from 28 high-risk patients with arthrodesis of the foot and ankle. (22) Union was reported for 24 (86%) cases at an average of 10 weeks; complications included breakage of the stimulator cables in 2 patients and hardware failure in 1 patient. Five patients required additional surgery. Prospective controlled trials are needed to evaluate this procedure.

The 1992 TEC Assessment indicated that semi-invasive bone growth stimulators are no longer in wide use. (12)

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2012

In response to requests, input was received from 5 academic medical centers while this policy was under review in 2012. The input supported use of noninvasive electrical bone growth stimulation for the treatment of fracture nonunions or congenital pseudoarthroses of the appendicular skeleton. Input agreed that noninvasive electrical bone growth stimulation is investigational for immediate post-surgical treatment after appendicular skeletal surgery and treatment of fresh fractures. A majority of reviewers considered the use of noninvasive electrical bone growth stimulation to be investigational for the treatment of delayed union, for arthrodesis, or for the treatment of failed arthrodesis.

Summary

There is evidence from randomized controlled trials (RCTs) and systematic reviews of clinical trials that noninvasive electrical stimulators improve fracture healing for patients with fracture non-union. This evidence is not from high-quality RCTs; however, and systematic reviews provide qualified support for this conclusion. Based on the available evidence and the lack of other options for patients with non-union, electrical stimulation may be considered medically necessary for the U.S. Food and Drug Administration (FDA)-approved indications of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton when specific criteria are met.

There is insufficient evidence to permit conclusions regarding the efficacy of noninvasive electrical bone growth stimulation for treatment of stress fractures or delayed union, or following surgery of the appendicular skeleton. In addition, a recent randomized trial found no benefit of electrical bone growth stimulation for fresh fractures. Use of noninvasive electrical bone growth stimulation for these conditions is considered investigational.

The literature for implantable bone stimulators of the appendicular skeleton consists of a small number of case series. In addition, no semi-invasive devices have FDA clearance or approval. The use of invasive or semi-invasive electrical bone growth stimulators is considered investigational.

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

The policy regarding electrical bone stimulation as an adjunct to spinal fusion surgery or as a treatment of failed spinal fusion surgery (i.e., salvage therapy) was initially based on 2 TEC Assessments (1, 2). The policy has been updated on a regular basis using MEDLINE literature searches; the searches have focused on review of controlled trials. The most recent literature search was conducted through August 26, 2013. The initial TEC Assessments (1, 2) offered the following conclusions:

- Data from a randomized, controlled clinical trial of patients meeting the criteria for high risk for development of failed fusion suggest that *invasive or noninvasive* electrical bone stimulation as an adjunct to spinal fusion surgery is associated with a significantly higher spinal fusion success rate in the treated group compared with the control group. (3, 4)
- Data from uncontrolled studies of patients with failed spinal fusion suggest that noninvasive electrical stimulation results in a significantly higher fusion rate. The lack of controlled clinical trials is balanced by the fact that these patients served as their own control.

Analysis of the data from clinical trials is limited by the following factors:

- Trials frequently include heterogeneous groups undergoing a variety of surgeries, which may have different risk levels for fusion failure.
- Trials frequently include patients undergoing spinal fusion both with and without additional surgical adjuncts, i.e., pedicle screws or back "cages," both designed to increase the fusion rate. Therefore, those patients undergoing instrumented spinal fusion procedures may have a decreased risk of fusion failure compared to those without instrumented procedures.
- While most trials have focused on "high-risk" patients, others have also included average-risk patients. The outcomes associated with average-risk patients are often not reported separately.
- Trials have used different outcomes for spinal fusion, based on varying clinical and radiologic outcomes.
- The presence or absence of spinal fusion may be considered an intermediate outcome, with the final health outcome typically focusing on relief of pain. Final health outcomes are typically not reported.

With the above limitations in mind, results of controlled trials are summarized below.

Implantable Electrical Stimulation

Instrumented Spinal Fusion

Kucharzyk reported on a controlled prospective nonrandomized trial of implantable electrical stimulation in patients undergoing instrumented posterior spinal fusion with pedicle screws. (5) A series of 65 patients who did not use electrical stimulation were compared with a later series of similar patients who did receive implantable electrical stimulation. Fusion success was 95.6% in the stimulated group compared to 87% in the nonstimulated group, a statistically significant difference. It appears that all patients had at least 1 or more high-risk factors for failed fusion, i.e., smoking history, prior surgery, multiple fusion levels, diabetes, etc. While this trial supports the use of electrical stimulation as an adjunct to instrumented posterior lumber fusion, it did not specifically identify the outcomes in patients considered to be at low risk for failed fusion. Rogozinski and Rogozinski reported on the outcomes of 2 consecutive series of patients undergoing posterolateral fusions with autologous bone graft and pedicle screw fixation. (6) The first series of 41 patients were treated without electrical stimulation, while the second group of 53 patients received invasive electrical stimulation. Those receiving electrical stimulation reported a 96% fusion rate, compared to an 85% fusion rate in the unstimulated group. The fusion rate for patients receiving stimulation versus no stimulation was also significantly higher among those considered at high risk due to previous back surgery or multiple fusion levels. No significant increase in the fusion rate was noted among nonsmokers (i.e., without a risk factor), but the comparative fusion rates for all patients without high-risk factors is not presented.

Noninstrumented Spinal Fusion

In 2009, Andersen et al. published 2-year radiographic and functional outcomes from a European multicenter randomized controlled trial (RCT) of direct current (DC) stimulation with the SpF-XL IIb for posterolateral lumbar spinal fusion (PLF) in 98 patients older than age 60 years. (7, 8) This age group has decreased fusion potential. In addition, instrumentation was not used due to risks related to longer operating times and screw loosening due to osteoporosis. All patients received fresh frozen allograft bone mixed with autograft obtained from the decompression procedure and were braced for 3 months after surgery. Dummy electrodes were placed in the control group to allow blinded radiographic evaluation, but patients and surgeons were not blinded to treatment group. Stimulator-specific complications included 3 cases of hematoma after removal of the battery and 2 patients who had pain at the site of the subcutaneous pocket. Three patients dropped out before the 1-year radiologic evaluation, 1 patient died, and an additional 25 patients did not complete the functional outcome questionnaires, resulting in 70% follow-up at 2-years. The percentage of dropouts was similar for the 2 treatments; patients who missed their 2-year evaluation had poorer outcomes on the Dallas Pain Questionnaire at the 1-year follow-up. Blinded evaluation of fusion by computed tomography (CT) scan indicated the same low percentage of cases with fusion in the 2 groups (33%). Fusion rates by plain radiographs were 57% in the control group (24/42) and 64% in the standard DC-stimulation group (27/42). Patients who achieved a solid fusion had better functional outcome and pain scores at their latest follow-up. At 2-year follow-up, electrical stimulation was associated with improved functional outcomes on 3 of 4 Dallas Pain Questionnaire subscales (daily activity, work/leisure, and social interest) but not for the Low Back Pain Rating Scale or the validated Short Form (SF)-36. These functional results have a high potential for bias due to the dropout of patients who had poorer outcomes and unequal patient expectation in this unblinded study.

In a 2010 publication, Anderson et al. evaluated bone quality of the fusion mass in 80 of the patients described above (82% of 98) who underwent dual energy x-ray absorptiometry (DEXA) scanning to evaluate bone mineral density (BMD) at the 1-year follow-up. (9) This report describes 40 (n=46) and 100 (n=8) microAmp DC stimulation compared with a nonstimulated control condition (n=36). Fusion rates determined by CT scanning at the 2-year follow-up were 34% in the control group and 33% and 43% in the 40 and 100 microAmp groups, respectively (not significantly different). Patients classified as fused after 2 years had significantly higher fusion mass BMD at 1 year (0.592 vs. 0.466 g/cm^2), but DC electrical stimulation did not improve fusion mass bone quality (0.483 g/cm^2 for 40 microAmp; 0.458 g/cm^2 for 100 microAmp; 0.512 g/cm^2 for controls). Using linear regression, fusion mass bone quality was significantly influenced by gender, age of the patient, bone density of the remaining part of the lumbar spine, amount of bone graft applied, and smoking.

No studies of semi-invasive (semi-implantable) stimulators were identified during the most recent literature search of MEDLINE through July 2011. In addition, none of these devices has U.S. Food and Drug Administration (FDA) clearance or approval. Thus, use of these devices is considered investigational.

Noninvasive Electrical Stimulation

Lumbar Spine

Goodwin and colleagues reported on the results of a study that randomly assigned 179 patients undergoing lumbar spinal fusions to receive or not receive capacitively coupled electrical stimulation. (10) A variety of surgical procedures both with and without instrumentation were used, and subjects were not limited to high-risk patients. The overall successful fusion rate was 84.7% for those in the active group compared to 64.9% in the placebo group, a statistically significant difference. While the actively treated group reported increased fusion success for all stratification groups (i.e., according to fusion procedure, single or multilevel fusion, smoking or nonsmoking group), in many instances, the differences did not reach statistical significance because of small numbers. For example, the subgroups in which there was not a significant difference in fusion between the active and placebo groups included patients who had undergone previous surgery, smokers, and those with multilevel fusion. In addition, there were numerous dropouts in the study and a 10% noncompliance rate with wearing the external device for up to 9 months.

Mooney reported on the results of a double-blind study that randomly assigned 195 patients undergoing initial attempts at interbody lumber fusions with or without fixation to receive or not receive pulsed electromagnetic field electrical stimulation. (4) Patients were not limited to high-risk groups. In the active treatment group, the success rate was 92%, compared to 65% in the placebo group. On subgroup analysis, the treated group consistently reported an increased success rate. Subgroups included graft type, presence or absence of internal fixation, or presence or absence of smoking.

Linovitz and colleagues conducted a double-blind clinical trial that randomly assigned 201 patients undergoing 1- or 2-level posterolateral fusion without instrumentation to undergo active or placebo electrical stimulation using a combined magnetic field device. (11) Unlike capacitively coupled or pulsed electromagnetic field devices, the combined magnetic field device requires a single 30-minute treatment per day with the device centered over the fusion site. Patients were treated for 9 months. Among all patients, 64% of those in the active group showed fusion at 9 months compared to 43% of those with placebo devices, a statistically significant difference. On subgroup analysis, there was a significant difference among women, but not men.

Mooney and Linovitz et al. excluded from their studies patients with severe osteoporosis, and Goodwin et al. excluded patients with osteoporosis of unspecified severity. (4, 10, 11) None of the studies mentioned steroid use; however, authors of two papers summarizing the available evidence on inhibition of bone healing (12) and the effects of drugs on bone healing (13) agree that long-term (longer than 1 week) steroid use has an inhibitory effect on bone healing. Thus, steroid use is added as an additional condition that results in high risk of nonfusion.

Cervical Spine

In 2008, Foley et al. published results of the industry-sponsored investigational device exemption (IDE) study of pulsed electromagnetic field (PEMF) stimulation as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft

interbody implants. (14, 15) This study described results using the Cervical-Stim device from Orthofix that received premarket approval (PMA) from the FDA in 2004. A total of 323 patients were randomized, 163 to PEMF and 160 to no stimulation. All patients were active smokers (more than 1 pack of cigarettes per day, 164 patients) or were undergoing multilevel ACDF (192 patients). Patients with pertinent history of trauma, previous posterior cervical approach or revision surgery, and certain systemic conditions or steroid use, and regional conditions such as Paget's disease or spondylitis were excluded. Beginning 1 week after surgery, patients in the treatment group wore the Cervical-Stim device for 4 hours per day for 3 months.

Efficacy was measured by radiographic analysis at 1, 2, 3, 6, and 12 months. At 6 months, 122 patients in the treatment group and 118 in the control group were evaluable; 15 in the PEMF group and 13 in the control group voluntarily withdrew, 7 in the PEMF group and 1 control violated study protocol, and 19 in the PEMF group and 28 controls had radiographs that were not evaluable or radiographs that were not done within 2 weeks of the 6-month postoperative window. Fusion rates for the 240 (74%) evaluable patients at 6 months were 83.6% for the PEMF group and 68.6% for the control group (p=0.0065). By intent-to-treat (ITT) analysis, assuming that nonevaluable patients did not have fusion, PEMF and control groups fusion rates were 65.6% and 56.3%, respectively; these rates were not significantly different (p=0.0835). (FDA analysis, however, indicated that the results at 6 months were still statistically different in sensitivity analysis performed with the last observation carried forward or with all missing data imputed as nonfusion.) Of 245 patients available for follow-up at 12 months, fusion was achieved in 116 of 125 (92.8%) PEMF patients and 104 of 120 (86.7%) control patients; these rates were not significantly different (p=0.1129). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not included in the paper.

Clinical outcomes were not reported in the 2008 publication but were reported to the FDA. With clinical success defined as no worsening in neurologic function, an improvement in visual analogue scale (VAS) pain assessment, and no worsening in Neck Disability Index, the study found no significant difference between groups in the percent of subjects considered a clinical success at 6 months (p=0.85) or 12 months (p=0.11). The marginal difference in fusion rates by ITT analysis at 6 months, nonsignificant difference in fusion rates at 12 months, and lack of difference in functional outcomes at either 6 or 12 months do not support the efficacy of this device.

The single other report of electrical stimulation as an adjunct to cervical fusion identified in searches of the MEDLINE database performed through August 2012 is a case report from 2004 that describes treatment with pulsed electromagnetic field stimulation for delayed union of anterior cervical fusion. (16)

Due to methodologic limitations in the only controlled trial published to date, the efficacy of electrical stimulation has not yet been established. Therefore, this technology is considered investigational for the cervical spine.

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from 2 physician specialty societies and 3 academic medical centers while this policy was under review for January 2011. Clinical input agreed with the criteria for high risk of fusion failure of the lumbar spine. The input on electrical stimulation for the cervical spine was mixed; specifically, some of those providing input agreed that data do not demonstrate improved outcomes with use of electrical stimulation in cervical spine fusion surgery. A majority of reviewers agreed that the large number of dropouts, nonsignificant difference in fusion rates by intent-to-treat analysis, and lack of data on functional outcomes (e.g., pain, return to usual activity) limited interpretation of the published study results.

Summary

Evidence from randomized controlled trials suggests that electrical stimulation leads to higher fusion rates for patients undergoing lumbar surgery. Interpretation of clinical trial data is limited by the heterogeneous populations studied and the variety of surgical procedures within the populations. Most patients in these studies were at high-risk for nonfusion, suggesting that the patients most likely to benefit are those at highest risk. The policy therefore indicates that electrical stimulation of the lumbar spine, whether invasive or noninvasive, should be limited to those patients with high-risk features. For patients at average risk for nonfusion, the scientific data are inadequate to determine the magnitude of benefit associated with electrical stimulation.

At present, the evidence does not demonstrate that electrical stimulation as an adjunct to fusion of cervical vertebrae improves health outcomes. In addition, clinical input regarding the efficacy of the technology was mixed. Therefore, electrical stimulation as an adjunct to fusion of cervical spine is considered investigational.

In addition, since there are no FDA-approved semi-invasive devices, these are considered investigational.

Practice Guidelines and Position Statements

The 2005 American Association of Neurological Surgeons and the Congress of Neurological Surgeons guideline states that there is Class II and III evidence (nonrandomized comparative trials and case series) “to support the use of direct current stimulation or capacitative coupled stimulation for enhancing fusion rates in high-risk patients undergoing lumbar PLF [posterolateral lumbar fusion]. A beneficial effect on fusion rates in patients not at "high risk" has not been convincingly demonstrated, nor has an effect been shown for these modalities in patients treated with interbody fusion. There is limited evidence both for and against the use of pulsed electromagnetic field stimulation (PEMFS) for enhancing fusion rates following PLF.

Class II and III medical evidence supports the use of PEMFS for promoting arthrodesis following interbody fusion. Although some studies have purported to demonstrate functional improvement in some patient subgroups, other studies have not detected differences. All of the reviewed studies are significantly flawed by the use of a 4-point patient satisfaction scale as the primary outcome measure. This outcome measure is not validated. Because of the use of this flawed outcome measure and because of the conflicting results reported in the better-designed studies that assess functional outcome, there is no consistent medical evidence to support or refute use of these devices for improving patient outcomes." (17)

Ultrasound Accelerated Fracture Healing Device

Literature Review

Fresh Fractures

The policy regarding fresh fractures is based in part on a 1995 TEC Assessment that concluded that ultrasound fracture healing met the TEC criteria for the indications labeled by FDA as a treatment of closed, fresh fractures of the tibial or distal radius (i.e., Colles') fractures. (2) Since the TEC Assessment, there have been numerous randomized controlled trials (RCTs) and systematic reviews of clinical trials on the use of ultrasound to improve healing in fresh fractures.

Systematic Reviews. A 2002 meta-analysis conducted by Busse and colleagues (3) supported the use of low-intensity ultrasound as a technique for fractures treated nonoperatively. This systematic review was updated in 2009 and included RCTs of low-intensity pulsed ultrasonography for any type of fracture. (4) Thirteen trials were included; in 5 of them, patients were managed conservatively, and in 8 studies, patients had ultrasound therapy after operative management (distraction osteogenesis in 3 studies, bone graft for nonunion in one, and operative treatment of fresh fractures in 4). Ultrasound therapy significantly accelerated radiographic healing of fractures in all 3 RCTs of conservatively managed fresh fractures that assessed this outcome. (These trials are described in more detail next.)

The trials of operatively managed (open) fresh fractures outcomes were inconsistent; 4 trials provided low-quality evidence for acceleration of healing by ultrasound therapy. Pooled results of 2 trials showed a nonsignificant mean reduction in radiographic healing time of 16.6%.

A 2012 Cochrane review on ultrasound and shockwave therapy included 11 studies on ultrasound; 8 of the studies were randomized controlled trials. (5) The included studies were limited in methodologic quality, with all having some evidence of bias. There was very limited evidence on functional outcomes, and the available data showed no significant difference between ultrasound and placebo control on functional outcomes. There was a significant effect of ultrasound on time to healing when all types of fractures were pooled (standardized mean difference -0.69, [95% confidence interval (CI), -1.31 to - 0.07]). This effect on time to healing

was not present when upper or lower limb fractures were examined separately and was not robust in sensitivity analyses performed as a "worst case analysis". There wasalso no significant treatment effect found in pooled analyses for treatment of nonunion or delayed union. This review did not distinguish between closed and open fractures.

RCTs of Closed Fractures. In a 1997 multicenter RCT by Kristiansen et al., 60 patients with dorsally angulated fractures of the distal radius treated with manipulation and cast were randomly assigned to 10 weeks of daily treatment with a pulsed ultrasound device or an inactive device. (6) All patients started ultrasound within 7 days after having sustained the fracture. Blinded radiographic and clinical examinations showed faster healing in the ultrasound group (61 days) than in the control group (98 days) ($p<0.001$). Each radiographic stage of healing also was significantly accelerated in the treatment group.

Heckman and colleagues performed a double-blind RCT comparing ultrasound treatment (n=33) with a placebo-control device (n=34) in closed or grade-I open fractures of the tibial shaft. (7) Treatment was started within 7 days after the fracture and consisted of one 20-minute period each day. Time-to-healing was 86 days in the treatment group versus 114 days in the control group ($p=0.01$), and time to overall (clinical and radiographic) healing was 96 days in the active-treatment group compared to 154 days in the control group ($p=0.0001$). Scaphoid fractures were treated with ultrasound in a study done in Germany. (8) Fifteen patients were randomly assigned to treatment and 15 to placebo device groups. Healing was assessed by computed tomography (CT) scans every 2 weeks. Fractures treated with ultrasound healed in 43.2 days versus 62 days in the control group ($p<0.01$). Pooled data from these studies demonstrated a mean reduction in radiographic healing time of 36.9% (95% CI, 25.6% to 46.0%).

Authors of another study included in the 2009 systematic review observed that the clinical relevance of accelerated radiologic healing has not been described and examined the effect of low-intensity pulsed ultrasound on fracture healing issues such as pain, function, and resumption of professional and personal activities. (9) They performed a multicenter double-blind RCT of ultrasound treatment of fresh clavicle fractures. Patients were taught to use the ultrasound devices for 20 minutes each day for 28 days and to record daily their subjective feeling as to whether the fracture healed or not (the primary outcome measure), pain on visual analogue scale (VAS), level of daily activities once a day expressed as hours of activity (work, household work, sport), and analgesic use. A total of 120 patients (61 active and 59 placebo) started study treatment. Nine patients in the active group and 10 in the placebo group were excluded from analysis because of incomplete follow-up or early withdrawal from the study. The day that the fracture clinically healed according to patient perception was determined in 92 patients (47 active and 45 placebo), and mean duration of time to clinical healing was 26.77 days in the active group versus 27.09 days in the placebo group. Between-group differences in analgesic use and mean VAS were not significant.

RCTs of Open Fractures and Surgically-treated Closed Fractures. For the treatment of open fractures, the data are conflicting regarding the efficacy of ultrasonic accelerated fracture healing

system (UAFHS), specifically those treated surgically with placement of an intramedullary nail. For example, Emami and colleagues conducted a study that randomly assigned 32 patients with a fresh tibial fracture that was fixed with an intramedullary rod to undergo additional treatment with an active or inactive ultrasound device. (10) The time-to-healing was not significantly different in the 2 groups, and the authors concluded that there was no benefit in operatively treated fractures. In contrast, Leung and colleagues reported on the results of a study that randomly assigned 30 fractures in 28 patients with complex tibial fractures treated with internal or external fixation to receive or not receive additional treatment with low-intensity ultrasound. (11) Based on radiologic assessment, the time to callus formation was significantly less in those in the ultrasound group. Due to the inconsistent results in the 2 small randomized studies, and the negative results of the meta-analysis, low-intensity ultrasound is considered investigational for open fractures.

In 2011 Dijkman et al. reported data from a substudy of 51 patients of a larger randomized controlled trial that enrolled patients with open or closed tibial shaft fractures that were treated surgically with an intramedullary nail. (12) According to the posting on online site www.Clinicaltrials.gov (NCT00667849), "the study was terminated due to futility", suggesting lack of benefit for this indication.

Section Summary

There is some RCT evidence that ultrasound treatment improves radiographic healing for closed fresh fractures, but this finding is not consistent for studies of open fresh fractures. A 2009 systematic review and meta-analysis of RCTs found moderate- to very low-quality evidence for low-intensity pulsed ultrasonography in accelerating functional recovery among patients with fracture. The systematic review concluded that large trials of high methodologic quality focusing on patient important outcomes such as quality of life and return to function are needed to determine whether ultrasound fracture healing devices provide important benefits to patients. A 2012 Cochrane review that did not distinguish between closed and open fractures reported that there was an improvement in time to healing when all studies were pooled but that this finding was not robust on further analyses. The Cochrane review did not find any evidence that ultrasound improves functional outcomes.

Nonunions

The policy regarding nonunion of fractures is based on data presented to the FDA as part of the approval process for Sonic Accelerated Fracture Healing System (SAFHS®) as a treatment of fracture nonunions. The following data were reported and are included in the package insert for the device (13):

- Data were collected on 74 cases of established nonunion with a mean fracture age of nearly 3 years. The principal outcome measure was the percentage of patients with healed nonunions, as determined clinically and by radiographic analysis. Each case served as its own control, based on the definition of nonunion that suggests that nonunions have a 0% probability of achieving a healed state without an intervention.

- A total of 64 of 74 cases (86%) were healed with use of low-intensity ultrasound. The time-to-healing was 173 days. The healed rate of scaphoid bones was lower, at 33% (2 of 6 cases), which was partially responsible for a significant difference between the healing rates of long bones (92%) versus other bones (67%).
- Fracture age also affected healing rates, with fractures over 5 years-old having a healing rate of 50% compared to a healing rate of 95% in those present for no more than 1 year.

A study used prospectively defined criteria for analysis of all Dutch patients (96 participating clinics) who had been treated with ultrasound for established nonunion of the tibia (characterized by a total stop of all fracture repair processes). (14) Included in the analysis were 71 patients who were at least 3 months from the last surgical intervention and did not show any healing improvements in the 3 months before ultrasound treatment (average fracture age: 257 days; range: 180–781 days). All patients were followed up (average 2.7 years) by questionnaire, or by phone, if needed. There was an overall healing rate of73%, at an average 184 days to healing (range: 52–739 days). No difference in healing rate for open or closed fractures was observed.

Delayed Union

In 2010, Schofer et al. reported an industry-sponsored multicenter randomized double-blinded sham-controlled trial of low-intensity pulsed ultrasound in 101 patients with delayed union of the tibia. (15) Delayed union was defined as lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 16 weeks from the index injury or the most recent intervention. Roughly one third of the patients had an open fracture. Fifty-one patients were randomized to daily treatment with ultrasound, and 50 were assigned to an inactive sham device (20 minutes daily for 16 weeks). The primary outcome measure was the change in bone mineral density (BMD) over the 16 weeks, assessed by computed tomography (CT) attenuation coefficients, or Hounsfield units (Hus). Gap area at the fracture site was a secondary endpoint. The primary analysis was intention-to-treat with imputation of missing values (24% of sham-treated subjects and 9.8% of active-treated subjects were missing post-treatment values). The mean improvement in BMD was 1.34 (90% CI, 1.14 to 1.57) times greater for ultrasound-treated subjects compared to sham. Analysis of ‘completers’ showed a medium effect size (0.53) of the treatment. A mean reduction in bone gap area also favored ultrasound treatment, with a mean change of log gap area of -0.131 mm2 for the active treatment and -0.097 mm2 for sham (effect size of -0.47, 95% CI, -0.91 to -0.03). Untransformed data showed a difference between groups of -0.457 mm2 (90% CI, -0.864 to -0.049), which was statistically significant by a 1-sided test. The clinical significance of this difference is unclear. There was a trend (p=0.07) for more subjects receiving low-intensity pulsed ultrasound to be judged to be healed by the participating physicians by the end of the 16- week study period, 65% (33 of 51) of ultrasound versus 46% (23 of 50) sham subjects. While there was not a statistically significant improvement in the rate of healing, the improvements in intermediate outcomes and the corroborating evidence from trials of patients with similar indications, e.g., fracture nonunion, make it very likely that this treatment is efficacious for delayed union.

Osteotomy Sites

In 2013, Urita et al. published a small (n=27) quasi-randomized study (alternating assignment) of low-intensity pulsed ultrasound after ulnar shortening osteotomy for ulnar impaction syndrome or radial shortening osteotomy for Kienbock disease. (16) Patients in the ultrasound group received once-daily 20- minute ultrasound treatments for at least 12 weeks postoperatively. Blinded evaluation of radiographic healing showed that ultrasound reduced the mean time to cortical union by 27% (57 vs. 76 days) and endosteal union by 18% (121 vs. 148 days). At the time of endosteal healing (mean of 121 or 148 days), the 2 groups had similar results on the Modified Mayo Wrist Score and no pain at the osteotomy site. Limitations of this study include the lack of a sham control and the long interval between the 16 and 24 week assessments, which may have increased group differences. In addition, clinical outcomes appear to have been assessed only at the time of radiographic healing and did not show any differences at this time point. Additional study is needed to determine with greater certainty the effect of low -intensity pulsed ultrasound on healing of osteotomy sites.

Distraction Osteogenesis

The 2009 systematic review by Busse et al. found 3 trials of distraction osteogenesis that used a variety of surrogate outcome measures with inconsistent results and provided very low-quality evidence of accelerated functional improvement. (4) In 2011, a small (n=36) nonblinded RCT of low-intensity pulsed ultrasound found no significant differences between the active and control groups in efficacy measures, although the treatment period (fixator gestation period) was decreased by more than a month. (17) Double-blind trials with a larger number of subjects are needed to evaluate the health benefits of this procedure.

Clinical Input Received Through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2008

In response to requests for input from physician specialty societies and academic medical centers for the 2008 policy update, input was received from 1 physician specialty society while this policy was under review. Physician input obtained through the American Academy of Orthopaedic Surgeons agreed with the positions regarding the criteria for medical necessity and the conditions that are considered investigational (e.g., delayed union and open/unstable grade II or III fractures).

2011

In response to requests, input was received through 2 physician specialty societies and 1 academic medical center for the policy review in January 2011. Input supported the use of ultrasound for nonunion and for fresh closed fractures at high risk for delayed fracture healing or nonunion as described in the policy. One reviewer supported including chemotherapy, immunosuppressive agents, history of infection, Charcot neuroarthropathy, and fractures of the tibial shaft or clavicle as additional risk factors, and a different reviewer supported including fractures of the talus and sesamoids as additional risk factors.

2012

In response to requests, input was received through 4 academic medical centers for the policy review in December 2012. Input supported the use of low-intensity ultrasound in delayed union and nonunion of bones excluding the skull and vertebra, and in fresh closed fractures at high risk for delayed fracture healing or nonunion. Input agreed that other applications of low-intensity ultrasound treatment are investigational, including, but not limited to, treatment of congenital pseudoarthroses, open fractures, stress fractures, arthrodesis or failed arthrodesis. Additional risk factors were noted, including: use of anticoagulants, immunosuppressive drugs or chemotherapy; infection at the fracture site; severe anemia; obesity; and fracture locations more prone to nonunion such as tibial and distal radial fractures.

Ongoing and Terminated Clinical Trials

The Trial to Evaluate Ultrasound in the Treatment of Tibial Fractures (TRUST) (NCT00667849) was a trial of low-intensity ultrasound for tibial fractures. This was a double-blind trial with sham ultrasound control, and was scheduled to enroll 500 patients with open or closed tibial fracture amenable to intramedullary nail fixation. The primary outcome measure was radiographic healing at up to one year, and a secondary outcome was the rate of fracture non-union. According to the posting on the online site www.Clinicaltrials.gov, "the study was terminated due to futility".An industry-sponsored randomized sham-controlled trial of low-intensity pulsed ultrasound for lumbar spine fusion (NCT00744861) was terminated after interim analysis. The primary outcome measure was radiographic fusion success at up to one year, and a secondary outcome was pain/disability. The study had a targeted enrollment of 310 patients with completion expected in 2012.

Summary

There is evidence from published studies that ultrasound improves healing rates in closed fresh fractures, delayed union, and fracture nonunion. As a result, ultrasound may be considered medically necessary for these indications. For treatment of open, fresh fractures, the evidence is less consistent across RCTs, and systematic reviews do not report strong conclusions on efficacy of ultrasound for improving healing when data on closed and open fresh fractures are combined. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization. Therefore, the most appropriate candidates for ultrasound treatment may be those with closed fractures at high risk for delayed fracture healing

or nonunion. Based on the available evidence and support from clinical input, low intensity ultrasound treatment may be considered medically necessary for fresh fractures (closed), delayed union of fractures, and nonunion of fractures.

Evidence is insufficient to evaluate health outcomes with use of low-intensity ultrasound as a treatment of congenital pseudarthroses, arthrodesis of the appendicular skeleton, or spinal fusions. Use of ultrasound for these conditions is considered investigational. Based on one small trial with results showing no benefit to use of ultrasound treatment in the treatment of stress fractures, this is considered investigational.

Practice Guidelines and Position Statements

The United Kingdom's National Institute for Health and Clinical Excellence (NICE) updated their guidance on low-intensity pulsed ultrasound for the treatment of non-union and delayed fracture healing in 2013. (18) NICE reached the following conclusions:
1.1 The case for adopting the EXOGEN ultrasound bone healing system to treat long-bone fractures with **non-union** (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.
1.2 The EXOGEN ultrasound bone healing system to treat long-bone fractures with **non-union** is associated with an estimated cost saving of £1164 per patient compared with current management, through avoiding surgery.
1.3 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.

The American Academy of Orthopaedic Surgeons (AAOS) published 2009 guidelines on the treatment of distal radius fractures. (19) The AAOS provided a weak recommendation for use of ultrasound for adjuvant treatment of distal radius fractures. This recommendation was based results from 2 studies that used non-validated patient outcome measures.

V. DEFINITIONS

TOP

APPENDICULAR SKELETON consists of the bones of the limbs and their girdles, attached to the axial skeleton.

AVASCULAR NECROSIS is the death of a segment of bone usually caused by insufficient blood flow to a region of the skeleton. It is also known as osteonecrosis.

POLICY TITLE	OSTEOGENIC STIMULATORS
POLICY NUMBER	MP-1.024

AXIAL SKELETON consists of bones in the head and trunk of the human body. It is composed of five parts; the human skull, the ossicles of the inner ear, the hyoid bone of the throat, the rib cage, and the vertebral column.

CONGENITAL PSEUDOARTHROSIS refers to a birth defect in the continuity of the tibia resulting in a separation or gap in the bone. The area is predisposed to fractures, which heal poorly.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

TOP

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Covered when medically necessary:

CPT Codes®								
20974	20975	20979						

POLICY TITLE	OSTEOGENIC STIMULATORS
POLICY NUMBER	MP-1.024

ICD-9 Procedure Codes	Description
78.90	Insertion of bone growth stimulator, unspecified site
78.91	Insertion of bone growth stimulator into scapula, clavicle and thorax (ribs and sternum)
78.92	Insertion of bone growth stimulator into humerus
78.93	Insertion of bone growth stimulator into radius and ulna
78.94	Insertion of bone growth stimulator into carpals and metacarpals
78.95	Insertion of bone growth stimulator into femur
78.96	Insertion of bone growth stimulator into patella
78.97	Insertion of bone growth stimulator into tibia and fibula
78.98	Insertion of bone growth stimulator into tarsals and metatarsals
78.99	Insertion of bone growth stimulator into other bone
99.86	Non-invasive placement of bone growth stimulator

HCPCS Code	Description
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, NON-INVASIVE

ICD-9-CM Diagnosis Code*	Description
713.5	ARTHROPATHY ASSOCIATED WITH NEUROLOGICAL DISORDERS
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 AND FIBULA
733.81	MELANIN OF FRACTURE
733.82	NONUNION OF FRACTURE
733.93	STRESS FRACTURE OF TIBIA OR FIBULA
812.00	CLOSED FRACTURE OF UNSPECIFIED PART OF UPPER END OF HUMERUS

POLICY TITLE	OSTEOGENIC STIMULATORS
POLICY NUMBER	MP-1.024

ICD-9-CM Diagnosis Code*	Description
812.01	CLOSED FRACTURE OF SURGICAL NECK OF HUMERUS
812.02	CLOSED FRACTURE OF ANATOMICAL NECK OF HUMERUS
812.03	CLOSED FRACTURE OF GREATER TUBEROSITY OF HUMERUS
812.09	OTHER CLOSED FRACTURES OF UPPER END OF HUMERUS
812.10	OPEN FRACTURE OF UNSPECIFIED PART OF UPPER END OF HUMERUS
812.11	OPEN FRACTURE OF SURGICAL NECK OF HUMERUS
812.30	OPEN FRACTURE OF UNSPECIFIED PART OF HUMERUS
812.31	OPEN FRACTURE OF SHAFT OF HUMERUS
812.40	CLOSED FRACTURE OF UNSPECIFIED PART OF LOWER END OF HUMERUS
812.41	CLOSED FRACTURE OF SUPRACONDYLAR HUMERUS
812.42	CLOSED FRACTURE OF LATERAL CONDYLE OF HUMERUS
812.43	CLOSED FRACTURE OF MEDIAL CONDYLE OF HUMERUS
812.44	CLOSED FRACTURE OF UNSPECIFIED CONDYLE(S) OF HUMERUS
812.49	OTHER CLOSED FRACTURE OF LOWER END OF HUMERUS
812.50	OPEN FRACTURE OF UNSPECIFIED PART OF LOWER END OF HUMERUS
812.51	OPEN FRACTURE OF SUPRACONDYLAR HUMERUS
812.52	OPEN FRACTURE OF LATERAL CONDYLE OF HUMERUS
812.53	OPEN FRACTURE OF MEDIAL CONDYLE OF HUMERUS
812.54	OPEN FRACTURE OF UNSPECIFIED CONDYLE(S) OF HUMERUS
812.59	OTHER OPEN FRACTURE OF LOWER END OF HUMERUS
813.00	UNSPECIFIED FRACTURE OF RADIUS AND ULNA, UPPER END OF FOREARM, CLOSED
813.01	CLOSED FRACTURE OF OLECRANON PROCESS OF ULNA
813.02	CLOSED FRACTURE OF CORONOID PROCESS OF ULNA
813.03	CLOSED MONTEGGIA'S FRACTURE
813.04	OTHER AND UNSPECIFIED CLOSED FRACTURES OF PROXIMAL END OF ULNA (ALONE)
813.05	CLOSED FRACTURE OF HEAD OF RADIUS
813.06	CLOSED FRACTURE OF NECK OF RADIUS
813.07	OTHER AND UNSPECIFIED CLOSED FRACTURES OF PROXIMAL END OF RADIUS (ALONE)
813.08	CLOSED FRACTURE OF RADIUS WITH ULNA, UPPER END (ANY PART)
813.10	UNSPECIFIED OPEN FRACTURE OF UPPER END OF FOREARM
813.11	OPEN FRACTURE OF OLECRANON PROCESS OF ULNA
813.12	OPEN FRACTURE OF CORONOID PROCESS OF ULNA
813.13	OPEN MONTEGGIA'S FRACTURE
813.14	OTHER AND UNSPECIFIED OPEN FRACTURES OF PROXIMAL END OF ULNA (ALONE)
813.15	OPEN FRACTURE OF HEAD OF RADIUS

POLICY TITLE	OSTEOGENIC STIMULATORS
POLICY NUMBER	MP-1.024

ICD-9-CM Diagnosis Code*	Description
813.16	OPEN FRACTURE OF NECK OF RADIUS
813.17	OTHER AND UNSPECIFIED OPEN FRACTURES OF PROXIMAL END OF RADIUS (ALONE)
813.18	OPEN FRACTURE OF RADIUS WITH ULNA, UPPER END (ANY PART)
813.20	UNSPECIFIED CLOSED FRACTURE OF SHAFT OF RADIUS OR ULNA
813.21	CLOSED FRACTURE OF SHAFT OF RADIUS (ALONE)
813.22	CLOSED FRACTURE OF SHAFT OF ULNA (ALONE)
813.23	CLOSED FRACTURE OF SHAFT OF RADIUS WITH ULNA
813.40	UNSPECIFIED CLOSED FRACTURE OF LOWER END OF FOREARM
813.41	CLOSED COLLES' FRACTURE
813.42	OTHER CLOSED FRACTURES OF DISTAL END OF RADIUS (ALONE)
813.43	CLOSED FRACTURE OF DISTAL END OF ULNA (ALONE)
813.45	TORUS FRACTURE OF RADIUS (ALONE)
813.50	UNSPECIFIED OPEN FRACTURE OF LOWER END OF FOREARM
813.51	OPEN COLLES' FRACTURE
813.52	OTHER OPEN FRACTURES OF DISTAL END OF RADIUS (ALONE)
813.53	OPEN FRACTURE OF DISTAL END OF ULNA (ALONE)
813.54	OPEN FRACTURE OF LOWER END OF RADIUS WITH ULNA
813.80	CLOSED FRACTURE OF UNSPECIFIED PART OF FOREARM
813.81	CLOSED FRACTURE OF UNSPECIFIED PART OF RADIUS (ALONE)
813.82	CLOSED FRACTURE OF UNSPECIFIED PART OF ULNA (ALONE)
813.83	CLOSED FRACTURE OF UNSPECIFIED PART OF RADIUS WITH ULNA
813.90	OPEN FRACTURE OF UNSPECIFIED PART OF FOREARM
813.91	OPEN FRACTURE OF UNSPECIFIED PART OF RADIUS (ALONE)
813.92	OPEN FRACTURE OF UNSPECIFIED PART OF ULNA (ALONE)
813.93	OPEN FRACTURE OF UNSPECIFIED PART OF RADIUS WITH ULNA
820.00	CLOSED FRACTURE OF UNSPECIFIED INTRACAPSULAR SECTION OF NECK OF FEMUR
820.01	CLOSED FRACTURE OF EPIPHYSIS (SEPARATION) (UPPER) OF NECK OF FEMUR
820.02	CLOSED FRACTURE OF MIDCERVICAL SECTION OF FEMUR
820.03	CLOSED FRACTURE OF BASE OF NECK OF FEMUR
820.09	OTHER CLOSED TRANSCERVICAL FRACTURE OF FEMUR
820.10	OPEN FRACTURE OF UNSPECIFIED INTRACAPSULAR SECTION OF NECK OF FEMUR
820.11	OPEN FRACTURE OF EPIPHYSIS (SEPARATION) (UPPER) OF NECK OF FEMUR
820.12	OPEN FRACTURE OF MIDCERVICAL SECTION OF FEMUR
820.13	OPEN FRACTURE OF BASE OF NECK OF FEMUR
820.19	OTHER OPEN TRANSCERVICAL FRACTURE OF FEMUR

POLICY TITLE	OSTEOGENIC STIMULATORS
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ICD-9-CM Diagnosis Code*	Description
820.20	CLOSED FRACTURE OF UNSPECIFIED TROCHANTERIC SECTION OF FEMUR
820.21	CLOSED FRACTURE OF INTERTROCHANTERIC SECTION OF FEMUR
820.22	CLOSED FRACTURE OF SUBTROCHANTERIC SECTION OF FEMUR
820.30	OPEN FRACTURE OF UNSPECIFIED TROCHANTERIC SECTION OF FEMUR
820.31	OPEN FRACTURE OF INTERTROCHANTERIC SECTION OF FEMUR
820.32	OPEN FRACTURE OF SUBTROCHANTERIC SECTION OF FEMUR
820.8	CLOSED FRACTURE OF UNSPECIFIED PART OF NECK OF FEMUR
820.9	OPEN FRACTURE OF UNSPECIFIED PART OF NECK OF FEMUR
821.00	CLOSED FRACTURE OF UNSPECIFIED PART OF FEMUR
821.01	CLOSED FRACTURE OF SHAFT OF FEMUR
821.11	OPEN FRACTURE OF SHAFT OF FEMUR
821.20	CLOSED FRACTURE OF UNSPECIFIED PART OF LOWER END OF FEMUR
821.21	CLOSED FRACTURE OF FEMORAL CONDYLE
821.22	CLOSED FRACTURE OF LOWER EPIPHYSIS OF FEMUR
821.23	CLOSED SUPRACONDYLAR FRACTURE OF FEMUR
821.22	CLOSED FRACTURE OF LOWER EPIPHYSIS OF FEMUR
821.23	CLOSED SUPRACONDYLAR FRACTURE OF FEMUR
821.29	OTHER CLOSED FRACTURE OF LOWER END OF FEMUR
821.30	OPEN FRACTURE OF UNSPECIFIED PART OF LOWER END OF FEMUR
821.31	OPEN FRACTURE OF FEMORAL CONDYLE
821.32	OPEN FRACTURE OF LOWER EPIPHYSIS OF FEMUR
821.33	OPEN SUPRACONDYLAR FRACTURE OF FEMUR
821.39	OTHER OPEN FRACTURE OF LOWER END OF FEMUR
823.00	CLOSED FRACTURE OF UPPER END OF TIBIA
823.01	CLOSED FRACTURE OF UPPER END OF FIBULA
823.02	CLOSED FRACTURE OF UPPER END OF FIBULA WITH TIBIA
823.10	OPEN FRACTURE OF UPPER END OF TIBIA
823.11	OPEN FRACTURE OF UPPER END OF FIBULA
823.12	OPEN FRACTURE OF UPPER END OF FIBULA WITH TIBIA
823.20	CLOSED FRACTURE OF SHAFT OF TIBIA
823.21	CLOSED FRACTURE OF SHAFT OF FIBULA
823.22	CLOSED FRACTURE OF SHAFT OF FIBULA WITH TIBIA
823.30	OPEN FRACTURE OF SHAFT OF TIBIA
823.31	OPEN FRACTURE OF SHAFT OF FIBULA
823.32	OPEN FRACTURE OF SHAFT OF FIBULA WITH TIBIA
823.40	TORUS FRACTURE OF TIBIA ALONE

POLICY TITLE	OSTEOGENIC STIMULATORS
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ICD-9-CM Diagnosis Code*	Description
823.41	TORUS FRACTURE OF FIBULA ALONE
823.42	TORUS FRACTURE OF FIBULA WITH TIBIA
823.80	CLOSED FRACTURE OF UNSPECIFIED PART OF TIBIA
823.81	CLOSED FRACTURE OF UNSPECIFIED PART OF FIBULA
823.82	CLOSED FRACTURE OF UNSPECIFIED PART OF FIBULA WITH TIBIA
823.90	OPEN FRACTURE OF UNSPECIFIED PART OF TIBIA
823.91	OPEN FRACTURE OF UNSPECIFIED PART OF FIBULA
823.92	OPEN FRACTURE OF UNSPECIFIED PART OF FIBULA WITH TIBIA
825.25	CLOSED FRACTURE OF METATARSAL BONE(S)
825.35	OPEN FRACTURE OF METATARSAL BONE(S)
996.4	MECHANICAL COMPLICATION OF INTERNAL ORTHOPEDIC DEVICE, IMPLANT, AND GRAFT
V54.17	AFTERCARE FOR HEALING TRAUMATIC FRACTURE OF VERTEBRAE
V54.27	AFTERCARE FOR HEALING PATHOLOGIC FRACTURE OF VERTEBRAE
V54.9	UNSPECIFIED ORTHOPEDIC AFTERCARE

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2014:

ICD-10-CM Diagnosis Code*	Description
	Ultrasound Accelerated Fracture Healing Device
S42.00xA – S42.92xA; S49.00xA – S49.199A; S52.00xA – S52.92xA; S59.00xA – S59.299A; S62.00xA – S62.92xA; S72.00xA – S72.92xA; S79.00xA – S79.199A; S82.00xA – S82.92xA; S89.00xA – S89.399A; S92.00xA – S92.919A	Fracture codes – 7th digit "A," as shown in the list, is initial encounter for closed fracture. The same codes with 7th digit "K" is subsequent encounter for nonunion (in forearm, femur, lower leg & ankle fractures 7th digits "M" and "N" are also nonunion for certain types of open fractures – in fractures of the shoulder, humerus, wrist, hand and foot there isn't separation of open vs. closed nonunions). This list does not include any skull or vertebral fracture codes. There are also other codes for pathological and stress fractures (M80 – M84) which are not listed here.
	Electrical Bone Growth Stimulation of the Appendicular Skeleton
S32.2xxK – S32.9xxK; S42.00xK – S42.92xK; S49.00xK – S49.199K;	Fracture nonunion codes for the appendicular skeleton – 7th digit "K" is subsequent encounter for nonunion (in forearm, femur, lower leg & ankle fractures 7th digits "M" and "N" are also nonunion for certain types of open fractures – in fractures of the shoulder, humerus, wrist, hand and foot there isn't separation of open vs. closed nonunions).

ICD-10-CM Diagnosis Code*	Description
S52.00xK – S52.92xN; S59.00xK – S59.299K; S62.00xK – S62.92xK; S72.00xK – S72.92xN; S79.00xK – S79.199K; S82.00xK – S82.92xN; S89.00xK – S89.399K; S92.00xK – S92.919K	
	Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion
M43.15-M43.17	Spondylolisthesis lumbar region code range
M48.05-M48.07	Spinal stenosis lumbar region code range
M51.04-M51.9	Thoracic, thoracolumbar, and lumbosacral intervertebral disc disorders code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES

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Electrical Bone Growth Stimulation of the Appendicular Skeleton

1. *Bhandari M, Fong K, Sprague S et al. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. J Bone Joint Surg Am 2012; 94(15):e1091-6.*
2. *Ahl T, Andersson G, Herberts P et al. Electrical treatment of non-united fractures. Acta Orthop Scand 1984; 55(6):585-8.*
3. *Connolly JF. Selection, evaluation and indications for electrical stimulation of ununited fractures. Clin Orthop Relat Res 1981; (161):39-53.*
4. *Connolly JF. Electrical treatment of nonunions. Its use and abuse in 100 consecutive fractures. Orthop Clin North Am 1984; 15(1):89-106.*
5. *de Haas WG, Beaupre A, Cameron H et al. The Canadian experience with pulsed magnetic fields in the treatment of ununited tibial fractures. Clin Orthop Relat Res 1986; (208):55-8.*
6. *Sharrard WJ, Sutcliffe ML, Robson MJ et al. The treatment of fibrous non-union of fractures by pulsing electromagnetic stimulation. J Bone Joint Surg Br 1982; 64(2):189-93.*

7. *Griffin XL, Warner F, Costa M. The role of electromagnetic stimulation in the management of established non-union of long bone fractures: what is the evidence? Injury 2008; 39(4):419-29.*
8. *Scott G, King JB. A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. J Bone Joint Surg Am 1994; 76(6):820-6.*
9. *Simonis RB, Parnell EJ, Ray PS et al. Electrical treatment of tibial non-union: a prospective, randomised, double-blind trial. Injury 2003; 34(5):357-62.*
10. *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.*
11. *Sharrard WJ. A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. J Bone Joint Surg Br 1990; 72(3):347-55.*
12. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation for delayed union or nonunion of fractures. TEC Assessment 1992:Volume 7:332-51.*
13. *Griffin XL, Costa ML, Parsons N et al. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. Cochrane Database Syst Rev 2011; (4):CD008471.*
14. *Barker AT, Dixon RA, Sharrard WJ et al. Pulsed magnetic field therapy for tibial non-union. Interim results of a double-blind trial. Lancet 1984; 1(8384):994-6.*
15. *Borsalino G, Bagnacani M, Bettati E et al. Electrical stimulation of human femoral intertrochanteric osteotomies. Double-blind study. Clin Orthop Relat Res 1988; (237):256-63.*
16. *Dhawan SK, Conti SF, Towers J et al. The effect of pulsed electromagnetic fields on hindfoot arthrodesis: a prospective study. J Foot Ankle Surg 2004; 43(2):93-6.*
17. *Adie S, Harris IA, Naylor JM 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- 76.*
18. *Hannemann PF, Gottgens 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):1403-8.*
19. *Beck BR, Matheson GO, Bergman G et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. Am J Sports Med 2008; 36(3):545-53.*
20. *Petrisor B, Lau JT. Electrical bone stimulation: an overview and its use in high risk and Charcot foot and ankle reconstructions. Foot Ankle Clin 2005; 10(4):609-20, vii-viii.*
21. *Lau JT, Stamatis ED, Myerson MS et al. Implantable direct-current bone stimulators in high-risk and revision foot and ankle surgery: a retrospective analysis with outcome assessment. Am J Orthop (Belle Mead NJ) 2007; 36(7):354-7.*
22. *Saxena A, DiDomenico LA, Widtfeldt A et al. Implantable electrical bone stimulation for arthrodeses of the foot and ankle in high-risk patients: a multicenter study. J Foot Ankle Surg 2005; 44(6):450-4.*

23. *Centers for Medicare and Medicaid Services. National Coverage Determination for Osteogenic Stimulators (150.2). 2005. Available online at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&DocID=150.2&list_type=ncd&bc=gAAAAAgAAAAAAA%3d%3d&. Accessed February 3, 2014.*

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

1. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation as an adjunct to spinal fusion surgery (invasive method). 1992 TEC Evaluations, pp. 324-51.*
2. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation in association with spinal fusion surgery (noninvasive method). 1993 TEC Evaluations, pp. 1-12.*
3. *Kane WJ. Direct current electrical bone growth stimulation for spinal fusion. Spine (Phila Pa 1976) 1988; 13(3):363-5.*
4. *Mooney V. A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions. Spine (Phila Pa 1976) 1990; 15(7):708-12.*
5. *Kucharzyk DW. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. Spine (Phila Pa 1976) 1999; 24(5):465-8; discussion 69.*
6. *Rogozinski A, Rogozinski C. Efficacy of implanted bone growth stimulation in instrumented lumbosacral spinal fusion. Spine (Phila Pa 1976) 1996; 21(21):2479-83.*
7. *Andersen T, Christensen FB, Egund N et al. The effect of electrical stimulation on lumbar spinal fusion in older patients: a randomized, controlled, multi-center trial: part 2: fusion rates. Spine (Phila Pa 1976) 2009; 34(21):2248-53.*
8. *Andersen T, Christensen FB, Ernst C et al. The effect of electrical stimulation on lumbar spinal fusion in older patients: a randomized, controlled, multi-center trial: part 1: functional outcome. Spine (Phila Pa 1976) 2009; 34(21):2241-7.*
9. *Andersen T, Christensen FB, Langdahl BL et al. Fusion mass bone quality after uninstrumented spinal fusion in older patients. Eur Spine J 2010; 19(12):2200-8.*
10. *Goodwin CB, Brighton CT, Guyer RD et al. A double-blind study of capacitively coupled electrical stimulation as an adjunct to lumbar spinal fusions. Spine (Phila Pa 1976) 1999; 24(13):1349-56; discussion 57.*
11. *Linovitz RJ, Pathria M, Bernhardt M et al. Combined magnetic fields accelerate and increase spine fusion: a double-blind, randomized, placebo controlled study. Spine (Phila Pa 1976) 2002; 27(13):1383-9; discussion 89.*
12. *Gaston MS, Simpson AH. Inhibition of fracture healing. J Bone Joint Surg Br 2007; 89(12):1553-60.*

13. *Pountos I, Georgouli T, Blokhuis TJ et al. Pharmacological agents and impairment of fracture healing: what is the evidence? Injury 2008; 39(4):384-94.*
14. *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):436-42.*
15. *U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Cervical-Stim Model 505L Cervical Fusion System. 2004. Available online at: http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030034b.pdf. Accessed February 3, 2014.*
16. *Mackenzie D, Veninga FD. Reversal of delayed union of anterior cervical fusion treated with pulsed electromagnetic field stimulation: case report. South Med J 2004; 97(5):519-24.*
17. *Resnick DK, Choudhri TF, Dailey AT et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. J Neurosurg Spine 2005; 2(6):737-40.*
18. *Centers for Medicare and Medicaid Services. National Coverage Determination for Osteogenic Stimulators (150.2). Available online at: http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=150.2&ncd_version=2&basket=ncd%3A150%2E2%3A2%3AOsteogenic+Stimulators. Accessed February 3, 2014.*

Ultrasound Accelerated Fracture Healing Device

1. *Bhandari M, Fong K, Sprague S et al. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. J Bone Joint Surg Am 2012; 94(15):e1091-6.*
2. *Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Ultrasound accelerated fracture healing. TEC Assessments 1995; Volume 10, Tab 14.*
3. *Busse JW, Bhandari M, Kulkarni AV et al. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. CMAJ 2002; 166(4):437-41.*
4. *Busse JW, Kaur J, Mollon B et al. Low intensity pulsed ultrasonography for fractures: systematic review of randomised controlled trials. BMJ 2009; 338:b351.*
5. *Griffin XL, Smith N, Parsons N et al. Ultrasound and shockwave therapy for acute fractures in adults. Cochrane Database Syst Rev 2012; 2:CD008579.*
6. *Kristiansen TK, Ryaby JP, McCabe J et al. 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 Am 1997; 79(7):961-73.*
7. *Heckman JD, Ryaby JP, McCabe J et al. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. J Bone Joint Surg Am 1994; 76(1):26-34.*
8. *Lubbert PH, van der Rijt RH, Hoorntje LE et al. Low-intensity pulsed ultrasound (LIPUS) in fresh clavicle fractures: a multi-centre double blind randomised controlled trial. Injury 2008; 39(12):1444-52.*
9. *Rue JP, Armstrong DW, 3rd, Frassica FJ et al. The effect of pulsed ultrasound in the treatment of tibial stress fractures. Orthopedics 2004; 27(11):1192-5.*

10. *Emami A, Petren-Mallmin M, Larsson S. No effect of low-intensity ultrasound on healing time of intramedullary fixed tibial fractures. J Orthop Trauma 1999; 13(4):252-7.*
11. *Leung KS, Lee WS, Tsui HF et al. Complex tibial fracture outcomes following treatment with low-intensity pulsed ultrasound. Ultrasound Med Biol 2004; 30(3):389-95.*
12. *Dijkman BG, Busse JW, Walter SD et al. The impact of clinical data on the evaluation of tibial fracture healing. Trials 2011; 12:237.*
13. *Summary of Safety and Effectiveness Data. Exogen 2000® or Sonic Accelerated Fracture Healing System (SAFHS®) Exogen®, a Smith and Nephew Company, Piscataway, NJ.*
14. *Rutten S, Nolte PA, Guit GL et al. Use of low-intensity pulsed ultrasound for posttraumatic nonunions of the tibia: a review of patients treated in the Netherlands. J Trauma 2007; 62(4):902- 8.*
15. *Schofer MD, Block JE, Aigner J et al. Improved healing response in delayed unions of the tibia with low-intensity pulsed ultrasound: results of a randomized sham-controlled trial. BMC Musculoskelet Disord 2010; 11:229.*
16. *Urita A, Iwasaki N, Kondo M et al. Effect of low-intensity pulsed ultrasound on bone healing at osteotomy sites after forearm bone shortening. J Hand Surg Am 2013; 38(3):498-503.*
17. *Dudda M, Hauser J, Muhr G et al. Low-intensity pulsed ultrasound as a useful adjuvant during distraction osteogenesis: a prospective, randomized controlled trial. J Trauma 2011; 71(5):1376- 80.*
18. *National Institute for Health and Care Excellence. NICE medical technology guidance 12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. 2013. Available online at: http://www.nice.org.uk/nicemedia/live/14018/62289/62289.pdf. Accessed February 3, 2014.*
19. *American Academy of Orthopaedic Surgeons. The treatment of distal radius fractures. 2009. Available online at: http://www.aaos.org/research/guidelines/drfguideline.pdf. Accessed February 3, 2014.*
20. *Centers for Medicare and Medicaid Services. National Coverage Decision for Osteogenic Stimulators (150.2) 2005. Available online at: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&DocID=150.2&list_type=ncd&bc=gAAAAAgAAAAAAA%3d%3d&. Accessed February 3, 2014.*

Other Sources

Durable Medical Equipment Regional Carrier (DME MAC A) Region A Local Coverage Determination (LCD) L11501). Osteogenic Stimulators. Effective 08/01/2009. [Website]: http://www.medicarenhic.com/dme/mrlcdcurrent.aspx Accessed February 3, 2014.

POLICY TITLE	OSTEOGENIC STIMULATORS
POLICY NUMBER	MP-1.024

X. POLICY HISTORY

TOP

MP 1.024	**CAC 5/27/03**
	CAC 12/2/03
	CAC 9/28/04
	CAC 9/27/05
	CAC 5/30/06
	CAC 2/27/07
	CAC 3/25/08
	CAC 5/26/09
	CAC 1/26/10 Minor Revision. Existing medically necessary policy statements modified by adding lumbar (spine) to the statements. Steroid use and current smoking habits added as another high-risk condition for non-fusion. New policy statements added that semi-invasive stimulators are investigational for lumbar spine fusion and that electrical bone-growth stimulators are investigational for use in cervical spine fusion. References updated.
	CAC 7/26/11 Adopt BCBSA. For Electrical Bone Growth Stimulation of the Appendicular Skeleton, the following indications has been removed from the policy statement: A non-healed osteotomy site, stress fractures, and treatment of Charcot foot disease (initial treatment immediately after surgical fusion. Electrical Bone Growth Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures risk criteria has been revised by deleting the information regarding multiple prior surgeries at risk for subsequent failed fusion (s). For Ultrasound Accelerated Fracture Healing Device, information was added regarding risk factors related to patient comorbidities and fracture locations that contribute to delayed fracture healing or nonunion of bones. An FEP variation was added. The Medicare variation was removed.
	Admin 1/4/12 Medicare variation placed on policy.
	CAC 4/24/12 Minor revision. Ultrasound accelerated fracture healing device is now considered medically necessary for delayed union in addition to fresh closed fracture and nonunion. **Expanded investigational applications of electrical bone growth stimulation.**
	CAC 6/4/13, Consensus list review. Administrative code review complete.
	CAC 3/25/14 Minor. For ultrasound accelerated fracture healing device • Changed current tobacco use to history of smoking. • Added nonunion of previously surgically-treated fractures as a medically necessary indication • Added fresh surgically-treated closed fractures and arthrodesis or failed arthrodesis as investigational indications Added policy guidelines defining fresh fracture and delayed union.

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	For electrical bone growth stimulation of the appendicular skeleton • Added clarification for compliance with non-weight bearing for fractures of pelvis and lower extremities. • Stress fractures added to investigational statement Rationale section added, References updated Added clarification for compliance with non-weight bearing for fractures of pelvis and lower extremities. Added reference to NCD 150.2 in Medicare variation. Policy coded.

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