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Bone Growth Stimulation

Policy # 00011

Original Effective Date: 05/1995

Current Effective Date: 09/17/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider both non-invasive and invasive electrical bone growth stimulation (EBGS) to be **eligible for coverage** when appropriate patient selection criteria are met.

Patient Selection Criteria for the use of Electrical Bone Growth Stimulation (EBGS) of the Appendicular Skeleton

Coverage eligibility for the use of non-invasive electrical bone growth stimulation (EBGS) of the appendicular skeleton will be considered when the following criteria are met:

- As treatment of fracture nonunion 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:

- o At least three months have passed since the date of fracture; and
- o Serial radiographs have confirmed that no progressive signs of healing have occurred; and
- o The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing.

Patient Selection Criteria for the use of Electrical Bone Growth Stimulation (EBGS) of the Spine

Coverage eligibility for the use of either non-invasive or invasive electrical bone growth stimulation (EBGS) will be considered when the following criteria are met:

- As an adjunct to spinal fusion surgery for patients with any of the following risk factors for subsequent failed fusion:
 - o One or more previous failed spinal fusion(s); or
 - o Grade III or worse spondylolisthesis; or
 - o Fusion to be performed at more than one level; or
 - o Smoking habit; or
 - o Diabetes; or
 - o Renal disease; or
 - o Alcoholism; or
 - o Steroid use.

Based on review of available data, the Company may consider noninvasive electrical bone stimulation as a treatment of patients with failed spinal fusion to be **eligible for coverage**. Failed spinal fusion is defined as

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a spinal fusion that has not healed at a minimum of six months after the original surgery, as evidenced by serial x-rays over a course of three months.

Based on review of available data, the Company may consider low-intensity ultrasound treatment 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 to be **eligible for coverage**.

Based on review of available data, the Company may consider low-intensity ultrasound treatment as a treatment of delayed union of bones excluding the skull and vertebra to be **eligible for coverage**.

Based on review of available data, the Company may consider low-intensity ultrasound treatment as a treatment of fracture non-unions of bones excluding the skull and vertebra to be **eligible for coverage**.

Patient Selection Criteria for the use of Low-intensity Ultrasound – Fresh Fracture

Coverage eligibility for low-intensity ultrasound will be considered when candidates for ultrasound treatment are at high risk for delayed fracture healing or nonunion. These risk factors may include either locations of fractures or patient comorbidities and include the following:

Patient comorbidities:

- Diabetes, renal disease or other metabolic diseases where bone healing is likely to be compromised
- Steroid therapy
- Osteoporosis
- History of alcoholism
- History of smoking

Fracture locations:

- Closed radial fractures, posteriorly displaced (Colles')
- Tibial diaphyseal fractures, closed or Grade I open
- 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

Patient Selection Criteria for the use of Low-intensity Ultrasound – Non-Union Fracture

Coverage eligibility for low-intensity ultrasound will be considered when the following criteria are met:

- At least three months have passed since the date of fracture; and
- Serial radiographs have confirmed that no progressive signs of healing have occurred; and
- The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing.



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When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on available data, the Company considers the use of invasive or non-invasive electrical bone growth stimulation (EBGS) to be **investigational*** when patient selection criteria are not met.

Based on available data, the Company considers other applications of non-invasive or invasive electrical bone growth stimulation (EBGS) including, but not limited to, the treatment of fresh fractures, delayed union, arthrodesis or failed arthrodesis to be **investigational***. (Note: *Delayed union is defined as a decelerating fracture healing process, as identified by serial x-rays.*)

Based on review of available data, the Company considers implantable and semi-invasive electrical bone growth stimulators for use on the appendicular skeleton to be **investigational.***

Based on review of available data, the Company considers semi-invasive electrical stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion to be **investigational.***

Based on available data, the Company considers the use of ultrasound bone growth stimulation to be **investigational*** when patient selection criteria are not met.

Based on available data, the Company considers other applications of low-intensity ultrasound treatment, including, but not limited to the treatment of congenital pseudarthroses, open fractures or stress fractures to be **investigational.***

Background/Overview

Electrical Bone Growth Stimulation of the Appendicular Skeleton

In the appendicular skeleton, electrical stimulation (with either implantable electrodes or non-invasive surface stimulators) is used in the treatment of fracture nonunion. Noninvasive EBGSs generate a weak electrical current using a variety of technologies, i.e., pulsed electromagnetic fields, capacitative coupling, or combined magnetic fields. 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. This concept has led to controversy regarding what constitutes long versus short bones. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levers 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. Thus the metatarsal is considered a long bone, while the scaphoid bone of the wrist is considered a short bone. Both the metatarsals and scaphoid bones are at a relatively high risk of nonunion after a fracture.

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Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. Cortical bone is always located on the exterior of the bone, while the trabecular bone is found in the interior. Each bone, depending on its physiologic function, has a different proportion of cancellous to trabecular bone. However, at a cellular level, both bone types are composed of lamellar bone and cannot be distinguished microscopically.

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

Both invasive and noninvasive EBGSSs are used as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the chances of obtaining a solid spinal fusion. Noninvasive devices may also be used to treat a failed fusion. Invasive devices use direct current; these 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. 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.

Noninvasive EBGSSs generate a weak electrical current within the target site using either 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 nine months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed into a back brace or directly onto the skin and are worn for 6 to 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 nine months. Patient compliance may be an issue with externally worn devices.

Ultrasound Accelerated Fracture Healing Device

Low-intensity pulsed ultrasound had been principally investigated as a technique to accelerate healing of fresh fractures, but more recently has been assessed as a treatment of fracture nonunions. Ultrasound can be delivered noninvasively with the use of a transducer applied to the skin surface overlying the fracture site. 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 deformation or indirectly by an electrical effect caused by cell deformation. The ultimate effect on fracture healing may be mediated by enhanced vascularity at the fracture site or enhanced chondrocyte maturation.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

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

Electrical Bone Growth Stimulation of the Appendicular Skeleton

The non-invasive OrthoPak® Bone Growth Stimulator (BioElectron) received FDA premarket approval (PMA) in 1984 for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket



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approval (all non-invasive 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 pseudarthroses.

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

The OsteoStim®‡ from Electro-Biology, Inc., an implantable device, received U.S. FDA PMA in 1984. The SpinalPak®‡ bone growth stimulator system, a capacitive coupling system, received PMA in 1999 for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels. Pulsed electromagnetic field systems with FDA PMA include the EBI Bone Healing System®‡ from Electrobiology, Inc., which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudarthroses; and the Cervical-Stim®‡ from Orthofix, which was approved in 2004 as an adjunct to cervical fusion surgery in patients at high risk for non-fusion.

Ultrasound Accelerated Fracture Healing Device

The Sonic Accelerated Fracture Healing System, SAFHS®‡ (also referred to as Exogen 2000®)‡ was initially cleared for marketing by the U.S. 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. According to the FDA labeling, a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

Centers for Medicare and Medicaid Services (CMS)

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Centers for Medicare and Medicaid Services cover noninvasive stimulators for the following indications:

- Nonunion of long bone fractures
- Failed fusion, where a minimum of nine months has elapsed since the last surgery
- Congenital pseudarthroses

Centers for Medicare and Medicaid Services cover invasive stimulators for the following indications:

- Nonunion of long bone fractures

Effective for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

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

Medicare covers noninvasive electrical stimulators for the following:

- Failed fusion, where a minimum of nine months has elapsed since the last surgery AND

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- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Medicare covers invasive electrical stimulators

- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Ultrasound Accelerated Fracture Healing Device

Effective January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion fractures. Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage. Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain non-covered.

Rationale/Source

Noninvasive Electrical Bone Growth Stimulation of the Appendicular Skeleton

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 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. It should be noted that the labeled indications include nonunions or congenital pseudoarthroses of bones of the appendicular skeleton. No distinction is made between long and short bones. The original FDA labeling of fracture nonunions defined nonunions as fractures that had not shown progressive healing after at least nine months from the original injury. This time frame is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. As mentioned, the presence of a nonunion is related to a variety of factors, such as fracture type and location, degree of soft tissue damage, vascularization, and bone stock. Some fractures may show no signs of healing, based on serial radiographs as early as three months, while a fracture nonunion may not be diagnosed in others until well after nine months. At the present time, the FDA has approved labeling changes for EGBSs that remove any time frame for the diagnosis. The current policy of requiring a 3-month time frame is still arbitrary, but appears to be consistent with the definition of nonunion, as described in the clinical literature.

The policy regarding electrical stimulation of delayed unions is based on a 1993 TEC Assessment, which offered the following conclusions:

- While data from a double-blind randomized controlled clinical trial (and additional long-term outcome data provided by the investigator) of patients with delayed unions suggests that a 12-week course of noninvasive electrical bone stimulation is associated with a significantly higher healing rate than a control group with a dummy device, there are inadequate data regarding the final health outcome of the patient, i.e., regained use of limb, minimal pain, avoidance of subsequent surgery. All patients in the trial had an unhealed fracture at an average of 23.8 weeks after injury; all fracture

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gaps were under 0.5cm. In terms of long-term outcome, a significantly greater proportion of the treated patients avoided any further surgery.

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. 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. 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 six cases of deep infection and five 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. Union was reported for 24 (86%) cases at an average of ten weeks; complications included breakage of the stimulator cables in two patients and hardware failure in one patient. Five patients required additional surgery. Prospective controlled trials are needed to evaluate this procedure.

A 2008 systematic review by Griffin and colleagues included 49 studies, 3 of which were randomized controlled trials. The first, a double-blind randomized controlled trial (RCT) by Sharrard, compared pulsed electromagnet field (PEMF) stimulation with a sham procedure using a dummy device, in 45 patients with nonunion of the tibia. Stimulators were positioned on the surface of the plaster cast. Treatment began 16 to 32 weeks after injury. Patients with fracture gaps greater than 0.5cm 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. Scott and King compared PEMF with sham treatment (dummy unit) in 23 patients with nonunion (fracture at least nine months old and without clinical or radiographic sign of progression to union within the last three months) of a long bone. 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 ($p=0.004$).

Simonis et al compared PEMF and placebo treatment for tibial shaft fractures un-united at least a year after fracture, no metal implant bridging the fracture gap, and no radiological progression of healing in the three months before treatment. 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 six months, and clinical and radiographic assessments were conducted at six months. Treatment was considered a failure if union was not achieved at six months. In the treatment group, 89% of fractures healed compared with 50% in the control group ($p=.02$). 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

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significant. The authors conclude that the available evidence supports the use of PEMF 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.

Invasive Electrical Bone Growth Stimulation of the Appendicular Skeleton

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. 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. 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. 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.

No studies of invasive or semi-invasive (semi-implantable) stimulators were identified in the literature search. The 1992 Technology Evaluation Center (TEC) Assessment indicated that semi-invasive bone growth stimulators are no longer in wide use.

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 5 academic medical centers. The input supported use of noninvasive EBGS for the treatment of fracture nonunions or congenital pseudoarthroses of the appendicular skeleton. Input agreed that noninvasive EBGS 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 EBGS to be investigational for the treatment of delayed union, for arthrodesis, or for the treatment of failed arthrodesis.

Summary

Evidence on noninvasive electrical stimulators is sufficient to consider this eligible for coverage for the treatment of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton when specific criteria are met.

There is insufficient evidence to evaluate the efficacy of noninvasive EBGS for the treatment of fresh fractures or delayed union. Use of noninvasive EBGS for these conditions is considered investigational.



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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 EGBSs are 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 two TEC Assessments. The initial TEC Assessments 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.
- 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. 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 one 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.

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Rogozinski and colleagues reported on the outcomes of two consecutive series of patients undergoing posterolateral fusions with autologous bone graft and pedicle screw fixation. 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 non-smokers (i.e., without a risk factor), but the comparative fusion rates for all patients without high-risk factors is not presented.

No studies of semi-invasive (semi-implantable) stimulators were identified. In addition, none of these devices has 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 randomized 179 patients undergoing lumbar spinal fusions to receive or not receive capacitively coupled electrical stimulation. 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 nine months.

Mooney and colleagues reported on the results of a double-blind study that randomized 195 patients undergoing initial attempts at interbody lumbar fusions with or without fixation to receive or not receive pulsed electromagnetic field electrical stimulation. 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 randomized 201 patients undergoing one- or two-level posterolateral fusion without instrumentation to undergo active or placebo electrical stimulation using a combined magnetic field device. 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 nine months. Among all patients, 64% of those in the active group showed fusion at nine 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.



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Moody and Linovitz excluded from their studies patients with severe osteoporosis and Goodman excluded patients with osteoporosis of unspecified severity. None of the studies mentioned steroid use, however authors of two papers summarizing the available evidence on inhibition of bone healing and the effects of drugs on bone healing agree that long-term (longer than one 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 non-fusion.

Cervical Spine

In 2008, Foley et al published results of the investigational device exemption study of PEMF stimulation as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants. This study described results using the Cervical-Stim device from Orthofix that received 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 one pack of cigarettes per day, 159 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 one week after surgery, patients in the treatment group wore the Cervical-Stim device for four hours per day for three months. Efficacy was measured by radiographic analysis at 1, 2, 3, 6, and 12 months. At six 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 two weeks of the 6-month postoperative window. Fusion rates for the 240 evaluable patients at six months were 83.6% for the PEMF group and 68.6% for the control group ($p = .0065$). By intent-to-treat analysis, assuming that nonevaluable patients did not have fusion, PEMF and control groups fusion rates were 65.6% and 56.3%, respectively ($p = .0835$). Of 245 patients available for follow-up at 12 months, fusion was achieved in 116 of 125 PEMF patients and 104 of 120 control patients ($p = .1129$). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not included in the paper. The large number of dropouts, non-significant difference in fusion rates by intent-to-treat analysis, and lack of data on functional outcomes (e.g., pain, return to usual activity) limit interpretation of these study results. No other studies of electrical stimulation as an adjunct to cervical fusion were identified in the literature search.

Summary

Interpretation of clinical trial data is limited by the heterogeneous populations studied, and the variety of surgical procedures within the populations. The policy indicates that electrical stimulation, whether invasive or noninvasive, should be limited to those patients with high-risk features. A review of the literature suggests that the patients most likely to benefit are those at highest risk. In addition, electrical stimulation may improve the fusion rate in patients undergoing both instrumented and non-instrumented surgeries. However, scientific data are inadequate to determine the magnitude of benefit associated with electrical stimulation in patients considered at average risk for fusion failure.

At present, the evidence is insufficient that electrical stimulation as an adjunct to fusion of cervical vertebrae improves fusion rates or functional outcomes. In addition, since there are no FDA-approved semi-invasive devices, these are also considered investigational.

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Ultrasound Accelerated Fracture Healing Device

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 the FDA as a treatment of closed, fresh fractures of the tibia or distal radius (i.e., Colles') fractures. 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 expansion of the policy to include 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.

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 Systems (SAFHS) as a treatment of fracture nonunions. The following data were reported and are included in the package insert for the device:

- Data were collected on 74 cases of established nonunion with a mean fracture age of nearly three 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 five years old having a healing rate of 50% compared to a healing rate of 95% in those present for no more than one year.

There are no controlled studies in the published literature that specifically addressed the use of low-intensity ultrasound as a treatment of delayed unions, congenital pseudarthroses, or spinal fusions. For healing of fresh fractures, the current policy limits its use to the treatment of closed fractures. Data are conflicting regarding the efficacy of ultrasonic accelerated fracture healing system (UAFHS) for the treatment of open fractures, specifically those treated surgically with placement of an intramedullary nail. For example, Emami and colleagues conducted a study that randomized 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. The time to healing was not significantly different in the two groups. These observations are consistent with a meta-analysis conducted by Busse and colleagues, whose analysis supported the use of low-intensity ultrasound as a technique for fractures treated nonoperatively. However, 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 randomized 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. 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 two small randomized studies, and the negative results of the meta-analysis, low-intensity ultrasound is still considered investigational for open fractures.

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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). Included in the analysis were 71 patients who were at least three months from the last surgical intervention and did not show any healing improvements in the three 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 of 73%, 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. 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 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 bone mineral density was 1.34 (90% confidence interval [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.

The 2009 systematic review and meta-analysis of RCTs described above found moderate to very low quality evidence for low-intensity pulsed ultrasonography in accelerating functional recovery among patients with fracture. For example, a study of non-operatively managed stress fractures in 26 midshipmen found no advantage for ultrasound therapy; treated subjects returned to active duty in a mean of 55.8 days versus 56.2 days for controls. Three trials of distraction osteogenesis used a variety of surrogate outcome measures with inconsistent results and provided very low-quality evidence of accelerated function improvement, and the trial of ultrasound therapy after bone graft for nonunion with 21 subjects provided low-quality evidence for a benefit for ultrasound therapy. Busse and colleagues advise that large trials of high methodologic quality focusing on patient important outcomes such as quality of life and return to



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function are needed to determine whether ultrasound fracture healing devices provide important benefits to patients.

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 the request for input from physician specialty societies and academic medical centers for the 2008 policy update, input was received from one 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).

In response to the request, input was received through two physician specialty societies and one 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.

Summary

Evidence is considered sufficient to conclude that ultrasound improves healing rates in closed fresh fractures, delayed union, and fracture nonunion. However, 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 at high risk for delayed fracture healing or nonunion.

Evidence is insufficient to evaluate health outcomes with use of low-intensity ultrasound as a treatment of congenital pseudarthroses, 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.

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Coding

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Code Type	Code
CPT	20974, 20975, 20979
HCPSC	C1816, C1883, E0747, E0748, E0749, E0760
ICD-9 Diagnosis	All relevant diagnoses
ICD-9 Procedure	78.90 thru 78.99, 99.86

Policy History

Original Effective Date:	05/1995
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10/18/2001	Medical Policy Committee review. Policy revised to include ultrasound accelerated healing devices and noninvasive and invasive bone growth stimulators.
11/12/2001	Managed Care Advisory Council approval
06/24/2002	Format revision. No substance change to policy.
11/18/2003	Medical Policy Committee review. Format revision. Policy name changed from Fracture Healing Devices to Bone Growth Stimulation.

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01/26/2004	Managed Care Advisory Council approval
03/01/2005	Medical Director review
03/15/2005	Medical Policy Committee review
04/04/2005	Managed Care Advisory Council approval
04/05/2006	Medical Director review
04/19/2006	Medical Policy Committee review. Format revision, including addition of FDA and or other governmental regulatory approval
04/04/2007	Medical Director review
04/18/2007	Medical Policy Committee approval. Coverage eligibility unchanged. Rationale/Source updated
04/02/2008	Medical Director review
04/16/2008	Medical Policy Committee approval. Coverage eligibility unchanged. Removed criterion from patient selection criteria 'the fracture gap is 1cm or less.' Rationale/Source updated.
04/02/2009	Medical Director review
04/15/2009	Medical Policy Committee approval. Coverage eligibility unchanged.
04/08/2010	Medical Policy Committee approval
04/21/2010	Medical Policy Implementation Committee approval. Added noninvasive electrical bone stimulation as a treatment of patients with failed lumbar spinal fusion to be eligible for coverage. Added implantable and semi-invasive electrical bone growth stimulators to be investigational. Added semi-invasive electrical stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion to be investigational. Added invasive, semi-invasive and noninvasive electrical stimulation as an adjunct to cervical fusion surgery and for failed cervical spine fusion to be investigational. Updated rationale and references.
04/07/2011	Medical Policy Committee review
04/13/2011	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
10/06/2011	Medical Policy Committee review
10/19/2011	Medical Policy Implementation Committee approval. "Based on review of available data, the Company may consider low-intensity ultrasound treatment may be considered as a treatment of delayed union of bones excluding the skull and vertebra to be eligible for coverage" was added to the coverage statement. Used to be investigational. "Based on available data, the Company considers implantable and semi-invasive electrical bone growth stimulators to be investigational" was removed from policy.
06/28/2012	Medical Policy Committee review
07/27/2012	Medical Policy Implementation Committee approval. Criteria for low –intensity ultrasound for fresh fractures revised.
02/20/2013	Medical Policy Implementation Committee approval. Changed criteria statement for electrical bone growth stimulation of the spine from "potential" spinal fusion surgery to "lumbar" spinal fusion surgery for clarification. Deleted the second criteria bullet for the use of electrical bone growth stimulation of the spine as a treatment for patients with failed spinal fusion, since this is a duplicate coverage statement in the policy.
06/06/2013	Medical Policy Committee review
06/25/2013	Medical Policy Implementation Committee approval. Replaced "lumbar" with "spinal" in the first bullet of the criteria for electrical bone growth stimulation of the spine, so that all spinal fusions are covered with criteria. Deleted "lumbar" from the non-invasive electrical bone growth stimulation coverage statement for failed spinal fusions. Deleted the investigational statement regarding cervical fusions.
09/05/2013	Medical Policy Committee review
09/18/2013	Medical Policy Implementation Committee approval. "Based on review of available data, the Company considers implantable and semi-invasive electrical bone growth stimulators for

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use on the appendicular skeleton to be investigational" was added to the coverage statement.

09/04/2014 Medical Policy Committee review

09/17/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.

Next Scheduled Review Date: 09/2015

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

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- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
 1. Consultation with the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated technology evaluation center(s);
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- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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