BlueCross BlueShield of Alabama

Name of Policy:
Electrical Bone Growth Stimulation of the Appendicular Skeleton

Policy #: 082
Category: DME
Latest Review Date: April 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *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.*

Proprietary Information of Blue Cross and Blue Shield of Alabama
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Description of Procedure or Service:

In the appendicular skeleton, electrical stimulation with either implantable electrodes or noninvasive surface stimulators has been investigated to facilitate the healing of fresh fractures, stress fractures, delayed union, nonunion, congenital pseudoarthrosis, and arthrodesis.

Delayed Fracture Healing

Most bone fractures heal spontaneously over a few months post injury. Approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services.

There is no standard definition of a fracture nonunion. The Food and Drug Administration (FDA) labeling for one of the electrical stimulators included in this review 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 a minimum of 3 months." Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables 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 from the original injury, or simply when serial radiographs fail to show any further healing. According to 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.” Factors contributing to a nonunion include: which bone is fractured, fracture site, degree of bone loss, time since injury, extent of soft tissue injury, and patient factors (e.g., smoking, diabetes, systemic disease).

Delayed union is generally considered a failure to heal between 3 and 9 months post fracture, after which the fracture site would be considered 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 fracture healing status, 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.

Fractures at certain locations (e.g., scaphoid, proximal fifth metatarsal) are at greater risk of delayed union due to a tenuous blood supply. Systemic factors, including immunosuppression, cancer, and tobacco use, may also predispose patients to fracture nonunion, along with certain medications (e.g., nonsteroidal anti-inflammatory drugs, fluoroquinolones).

Treatment

Electrical and Electromagnetic Bone Growth Stimulators

Different applications of electrical and electromagnetic fields have been used to promote healing of delayed and nonunion fractures: invasive, noninvasive, and semi-invasive.

Invasive stimulation involves the surgical implantation of a cathode at the fracture site to produce direct current 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 a day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils placed over the skin and worn for 6 to 8 hours a 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.

Fracture Nonunion

There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture healing for at least three consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing) (Bhandari, 2012).

The original U. S. Food and Drug Administration (FDA) labeling of fracture nonunions defined nonunions as fractures that had not shown progressive healing after at least 9 months from the original injury. The original 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". This timeframe 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. Others have contended that 9 months represents an arbitrary cutoff 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. Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial x-rays, 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. In contrast, nonunion serial x-rays (described next) show no evidence of healing.

When lumped together, delayed union and nonunion are sometimes referred to as "ununited fractures".

Fresh 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.

For Electrical Bone Stimulation for the Spine, please refer to policy *#524, Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion*.

Policy:

Noninvasive electrical bone growth stimulation (E0747) meets Blue Cross and Blue Shield of Alabama’s medical criteria for coverage as treatment of fracture nonunions or congenital pseudarthroses in the appendicular skeleton (the appendicular skeleton includes bones of the shoulder girdle, upper extremities, pelvis and lower extremities) for the following:

- The diagnosis of **fracture nonunion** when **meets all the following criteria**:
  - The fracture must be of at least 90 days duration;
  - Serial imaging confirms that no progressive healing has occurred;
  - Fracture gap is ≤1 cm; **and**
  - The individual can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.
- Failed joint fusion following arthrodesis ankle or knee (failed joint fusion is defined as a joint fusion that has not healed at a minimum of 6 months after the arthrodesis, as evidenced by serial imaging over a course of 3 months);
- When used in conjunction with surgical intervention for treatment of an established nonunion;
- Stress fracture that has a failed union after 90 days of treatment.

Electrical bone growth stimulation does not meet Blue Cross and Blue Shield of Alabama’s medical criteria for coverage and is considered **investigational** for, but not limited to the following applications:

- Immediate post-surgical treatment after appendicular skeletal surgery
- Treatment of fresh fractures
- Delayed or incomplete union fractures
- Fractures of the skull
- Lunate fractures
- Spondylosis
- Synovial pseudarthroses
- Draining osteomyelitis
- Fresh bunionectomies
- Severe osteoporosis
- Significant motion at the fracture site

- In patients with a demand-type pacemaker or an implantable cardioverter defibrillator

Invasive and semi invasive electrical bone growth stimulators (E0749) do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage and are considered **investigational**.

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The policy is updated on a regular basis using the MEDLINE database. The most recent literature update was conducted through February 05, 2018.

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Noninvasive Bone Growth Stimulation

Fracture Nonunion

As noted, there is no consensus for the definition of nonunion. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and for at least 6 months following the fracture) accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty bearing weight).

The U.S. Food and Drug Administration (FDA) approval of electrical bone growth stimulation as a treatment of fracture nonunion involving the appendicular skeleton. FDA approval was based on a number of case series in which patients with nonunions, primarily of the tibia, served as their own controls. These studies from the 1980s have suggested that electrical stimulation results in subsequent unions in a significant percentage of patients.

Systematic Reviews

Aleem et al (2016) reported a systematic review and meta-analysis on the efficacy of electrical stimulators for bone healing. The review was reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. Reviewers searched MEDLINE, EMBASE, CINAHL, and the Cochrane Library up to March 6, 2016, supplemented with hand searches of major orthopedic conference proceedings from March 2013 to March 2016, for RCTs comparing direct current, capacitive coupling, or pulsed electromagnetic field (PEMF) therapy to sham control for nonunion, delayed union, fresh fracture, osteotomy, or symptomatic spinal instability requiring fusion. Analyses were performed with the intention-to-treat principle using random-effects models. Fifteen trials were identified, of which 5 included treatments of nonunion or delayed-union fractures. Nonunion or delayed-union fractures were combined in subgroup analyses including 174 participants. The estimated relative risk for electrical stimulators versus sham for the outcome of radiographic nonunion at the last follow-up or 12 months was 0.57 (95% confidence interval [CI], 0.29 to 1.12; I^2=76%; p=0.002). Overall reviewers found no evidence to support a difference in treatment effect due to treatment indication (interaction p=0.75) and moderate quality evidence supporting electrical stimulation in reducing patient-reported pain and radiographic nonunion across indications. The 2 largest and most recent trials of nonunion fractures are described in the following section.

Griffin et al (2008) reported on a systematic review of electromagnetic bone growth stimulation that included 49 studies, 3 of which were randomized controlled trials (RCTs). The 2 RCTs that included patients with nonunion are described next.

Randomized Controlled Trials

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 signs of progression to union within the last 3 months) of a long bone. In this trial, electrodes were passed onto the skin surface through holes in the plaster cast. Twenty-one patients completed the protocol (10 treatments, 11 controls). Six months after patients began treatment, an orthopedic surgeon and a radiologist, neither of whom were involved in patient 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 PEMF stimulation and placebo treatment for tibial shaft fractures ununited at least 1 year after fracture, with no metal implant bridging the fracture gap, and no radiographic progression of healing in the 3 months before treatment. All 34 patients received surgical treatment with osteotomy and unilateral external fixator before randomization. Treatment was delivered by external coils; control subjects received sham treatment at identical machines not passing current through the 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% (16/18) of fractures healed compared with 50% (8/16) in the control group (p=0.02). While a larger percentage of smokers in the treatment group healed compared with those in the control group, there was an imbalance in the number of smokers in each group, and the difference in healing rates between groups was not statistically significant. The authors concluded that the available evidence supported the use of PEMF therapy in the treatment of nonunion of the tibia and suggested that future trials consider which electromagnetic stimulation modality and for which anatomic sites the treatment is most effective.

Section Summary: Fracture Nonunion
Sham-controlled randomized trials with fewer than 60 patients in total have concluded that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. Pre-post studies of patients with nonhealing fractures have also suggested the efficacy of this treatment. There are few nonsurgical options in this population.

Delayed Fracture Union
Systematic Reviews
The Aleem (2016) review (discussed previously) reported a combined meta-analysis for delayed and nonunion fractures. Similarly, the Griffin (2008) review also combined delayed and nonunion fractures. The 2 included RCTs (n=92 patients) of delayed fractures included in both reviews are described in the following section.

The portion of the evidence review on electrical stimulation of delayed unions is based on a 1992 TEC Assessment of the RCT by Sharrard (described in the following section), which offered the following conclusions: "…Sharrard's health outcome data do not show that noninvasive electrical bone growth stimulation delivers an advantage over placebo."

Randomized Controlled Trials
Shi et al (2013) 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). 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 nine months, were excluded from the study. Treatment with eight hours of PEMF per day was stopped when no radiographic progression was observed over three 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. 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 treatments and 25 controls). In the treatment group, three patients achieved union, two achieved probable union, five showed progression to union, and 10 showed no progress after 12 weeks. In the control group, none had united, one had probably united, three progressed toward union, and 17 showed no progress.

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. 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. Thus, four 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: Delayed Fracture Union

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 (eight hours a day) in 32 patients who underwent femoral intertrochanteric osteotomy for osteoarthritis of the hip. 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. 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.

Section Summary: Appendicular Skeletal Surgery
The evidence on the use of noninvasive electrical bone growth stimulation to treat those who have had surgery of the appendicular skeleton consists of several RCTs. The trials showed some benefit of stimulation treatment, but clinical outcomes of interest were not assessed, limiting conclusions that can be drawn about treatment efficacy.

Fresh Fractures
Systematic Reviews
The Aleem (2016) systematic review (described previously) also included subgroup analyses for fresh fractures with the outcome of radiographic nonunion at last reported follow-up (to 12 months) for electrical stimulators versus sham. Five trials (total N=366 patients) were included. The combined relative risk of radiographic nonunion was 0.83 (95% CI, 0.51 to 1.35; I^2=11%; p=0.35). The selected trials were of moderate-to-high quality. The 2 largest trials are summarized below.

Randomized Controlled Trials
Adie et al (2011) reported results of a multicenter, double-blind, randomized sham-controlled trial evaluated 12 weeks of pulsed electromagnetic field stimulation for acute tibial shaft fractures. The end points 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 union or nonunion within 12 months after the injury, was similar for the two 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 six 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.

Hanneman et al (2014) reported a multicenter double-blind, randomized sham-controlled trial (n=102) conducted in the Netherlands, that found little advantage of 6 weeks of PEMF for the treatment of fresh (≤5 days from injury) scaphoid fractures. Outcomes included the time to clinical and radiologic union and functional outcome at 6, 9, 12, 24, and 52 weeks. Radiologic union measured by computed tomography was not significantly different between the 2 groups. The median time to clinical union was 6 weeks in both groups. The return to normal range of movement at the wrist was 12 weeks in both groups. Grip strength of the dominant hand returned to normal earlier with PEMF, but there was no significant difference in return of grip strength of the non-dominant hand. Functional outcomes were reported in 2015. There were no significant differences in either the pain or the function subscales of the Patient- Rated Hand/Wrist Evaluation between the PEMF group and the sham group at any of the 5 follow-up time points. Each of the 5 domains of the EuroQol-5D as well as the EuroQoL VAS were also

compared at each time point. There was 1 marginally significant difference in these domain scores (anxiety/depression domain at week 24), which would have been expected by chance given the number of statistical tests performed. The mean number of working days lost were similar in 2 group (10 days vs 13 days; p=0.65), and the total mean quality-adjusted life years were 0.84 and 0.85 for PEMF versus sham (difference =0.01; 95% CI, -0.01 to 0.04), respectively.

Section Summary: Fresh Fracture(s)
Five RCTs including 366 participants have compared electrical stimulators with sham in the treatment of fresh fractures. A systematic review and meta-analysis of these trials found moderate-quality evidence that the risk of radiographic nonunion is about 17% lower in participants treated with electrical stimulators compared to sham, but this difference was not statistically significant. No differences in functional outcomes were reported between electrical stimulators and sham.

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. 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.

Section Summary: Stress Fractures
The evidence on the use of noninvasive electrical bone growth stimulation to treat stress fractures consists of an RCT. In this well-constructed trial, there was no difference in the healing rates between the stimulation and placebo groups.

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 Petrisor and Lau, 2005). 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 10 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.

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

Section Summary: Invasive Bone Growth Stimulation
The evidence on the use of implantable and semi-invasive electrical bone growth stimulation to treat fractures, pseudoarthroses, or those who have had surgery of the appendicular skeleton consists of a small number of case series, reporting on small numbers of patients. Prospective controlled trials are needed to evaluate this procedure.

Summary of Evidence

Noninvasive Electrical Bone Growth Stimulation

For individuals who have fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration has approved noninvasive electrical bone growth stimulation for fracture nonunions and congenital pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their own controls. There is also evidence from 2 small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. However, there are few nonsurgical options in this population, and the pre-post studies of patients with nonhealing fractures support the efficacy of the treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have delayed fracture union, fresh or stress fracture(s), or who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of 5 RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. RCTs on delayed union of the other types of fractures were limited by small sample sizes and did not show significant differences in outcomes between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

Invasive Electrical Bone Growth Stimulation

For individuals who have fracture, pseudoarthroses, or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive electrical bone growth stimulation, the evidence includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Key Words:

Fracture, nonunion, delayed union, bone growth stimulator, electrical bone growth stimulator, osteogenesis stimulator, invasive, semi-invasive, non invasive, electrical current, percutaneous, pseudarthrosis, pseudoarthrosis, Exogen 2000™, Exogen 3000, SAFHS® Model 2A, SAFHS® Model 2000, EBI Bone Healing System®, EBI OsteoGen OrthoPak®, Physio-Stim Lite®, Dynatron STS, Zimmer Direct Bone Growth Stimulator, Orthofix, OsteoStim®

Approved by Governing Bodies:

In 1984, the noninvasive OrthoPak® Bone Growth Stimulator (BioElectron, now Zimmer Biomet) was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all noninvasive devices) include Physio-Stim® (Orthofix), 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® (Electrobiology Inc., now Zimmer Biomet), which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. No distinction was made between long and short bones. FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis.

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

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

20974	Electrical stimulation to aid bone healing; non-invasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes:

E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal application
E0749	Osteogenesis stimulator, electrical (surgically implanted)

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Policy History:

Medical Policy Group, October 2008 **(4)**
Medical Policy Administration Committee, November 2008
Available for comment November 20, 2008-January 5, 2009
Medical Policy Group, February 2009 **(4)**
Medical Policy Administration Committee, March 2009
Available for comment February 27-April 13, 2009
Medical Policy Group, October 2009 **(1)**
Medical Policy Administration Committee, October 2009
Available for comment October 20-December 3, 2009
Medical Policy Group, November 2009 **(1)**
Medical Policy Administration Committee, December 2009
Available for comment December 4, 2009-January 19, 2010
Medical Policy Group, February 2010 **(1)**
Medical Policy Administration Committee, April 2010
Available for comment April 7-May 21, 2010
Medical Policy Group, February 2010; Regular update **(1)**
Medical Policy Group, November 2011 **(1):** Electrical bone growth stimulators separated from policy #331; Update to Key Points and References; no change in policy statement
Medical Policy Administration Committee, January 2012
Available for comment January 11 – February 27, 2012
Medical Policy Panel, October 2012
Medical Policy Group, March 2013 **(1):** Electrical Stimulation of the Spine separated from this policy and moved to new policy #524, information box added to direct to new policy; Title change to reflect Appendicular Skeleton; Update to Key Points and Reference; no change in policy statement
Medical Policy Panel, January 2014
Medical Policy Group, January 2014 **(1):** Update to Key Points and References; no change to policy statement
Medical Policy Panel, December 2014
Medical Policy Group, December 2014 **(5):** Updates to Description, Key Points and References. No change to policy statement.
Medical Policy Group, August, 2015 **(6):** Reorganized policy statement text; no change to policy intent.
Medical Policy Group, February 2016 **(6)**: Clarification to policy statement regarding coverage of pelvis and scapula; no change to policy intent.
Medical Policy Panel, April 2016
Medical Policy Group, April 2016 **(6):** Updates to Description and Key Points; no change to policy statement.
Medical Policy Panel, April 2017
Medical Policy Group, May 2017 (**6**): Updates to Description, Key Points, Governing Bodies and References.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(6)**: Updates to Key Points.

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plans contracts.