7.01.07	Electrical Bone Growth Stimulation of the Appendicular Skeleton		
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Section:	7.0 Surgery	**Page:**	Page 1 of 14

Policy Statement

Noninvasive electrical bone growth stimulation, in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) may be considered **medically necessary** as treatment for **either** of the following conditions:

- Congenital Pseudoarthroses
- Fracture Nonunions must meet **all** of the following criteria:
  - At least 3 months have passed since the date of fracture
  - Serial radiographs have confirmed that no progressive signs of healing have occurred
  - The fracture gap is 1 cm or less
  - The patient can be adequately immobilized
  - The patient is of an age likely to comply with nonweight bearing for fractures of the pelvis and lower extremities

Applications of electrical bone growth stimulation are considered **investigational** for **all** indications including, but are not limited to:

- Arthrodesis, or failed arthrodesis
- Delayed union
- Fresh fracture
- Immediate postsurgical treatment after appendicular skeletal surgery
- Stress fractures

Implantable and semi-invasive electrical bone growth stimulators are considered **investigational**.

Policy Guidelines

Fracture Nonunion

No consensus on the definition of fracture nonunion currently exists. 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) (Bhandari et al, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: "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 present in fractures (i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, 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 radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. In contrast, nonunion serial radiographs (described above) 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 its occurrence. Most fresh closed fractures heal without complications with the use of standard fracture care (i.e., closed reduction, cast immobilization).

Coding
There are specific CPT codes that describe electrical bone growth stimulation:

- **20974**: Electrical stimulation to aid bone healing; noninvasive (nonoperative)
- **20975**: Electrical stimulation to aid bone healing; invasive (operative)

There are specific HCPCS codes that describe electrical bone growth stimulation:

- **E0747**: Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
- **E0749**: Osteogenesis stimulator, electrical, surgically implanted

Description

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 pseudoarthroses, and arthrodesis.

Related Policies

- Bone Morphogenetic Protein
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
- Ultrasound Accelerated Fracture Healing Device

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

In 1984, the noninvasive OrthoPak® Bone Growth Stimulator (BioElectron, now Zimmer Biomet) was approved by the FDA through the premarket approval process for treatment of fracture nonunion. Pulsed electromagnetic field systems with the 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, 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. The 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 the FDA approval or clearance were identified.

FDA product code LOF.

Rationale

Background

Delayed Fracture Healing

Most bone fractures heal spontaneously over a few months postinjury. Approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services.[1,]

There is no standard definition of a fracture nonunion.[2,]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 nine months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures (i.e., the degree of soft tissue damage, alignment of the bone fragments, vascularity, quality of the underlying bone stock). Other proposed definitions of nonunion involve three to six months from the original injury, or simply when serial radiographs fail to show any further healing. According to the FDA labeling for a low-intensity pulsed ultrasound device, “a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.” Factors contributing to a nonunion include: which bone is fractured, fracture site, the degree of bone loss, time since injury, the extent of soft tissue injury, and patient factors (e.g., smoking, diabetes, systemic disease).[1,]

Delayed union is generally considered a failure to heal between three and nine months postfracture, 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

Individuals with recognized delayed fracture unions might begin by reducing the risk factors for delayed unions or nonunions but may progress to surgical repair if it persists.

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 six to nine 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 six to eight hours a day for three to six 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.

Literature Review

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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.

Clinical Context and Therapy Purpose

The purpose of electrical bone growth stimulation of the appendicular skeleton in patients with fractures or who have had bone surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does electrical bone growth stimulation of the appendicular skeleton improve the net health outcome in patients with fractures or who have had bone surgery?

The following PICOTS were used to select literature to inform this review.

Patients
The relevant populations of interest are patients who have had fractures or surgery of the appendicular skeleton.

Interventions
The therapy being considered is electrical bone growth stimulation.

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. Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive 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.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation of the appendicular skeleton: for patients who have had fractures, relevant comparators are conservative therapy and surgery. For patients who have had surgery of the appendicular skeleton, relevant comparators are standard post-surgical therapies.

Outcomes
The general outcomes of interest are symptoms, change in disease status, and functional outcomes.

Noninvasive Electrical Bone Growth Stimulation
Fracture Nonunion
As noted, there is no consensus on the definition of nonunion. One proposed definition is the failure of progression of fracture healing for at least three consecutive months (and for at least six months following the fracture) accompanied by clinical symptoms of delayed union or nonunion (pain, difficulty bearing weight).[2,]

U.S. Food and Drug Administration approval of electrical bone growth stimulation as a treatment of fracture nonunion involving the appendicular skeleton was based on a number of case series in which patients with nonunions, primarily of the tibia, served as their controls. These studies from the 1980's have suggested that electrical stimulation results in subsequent unions in a significant percentage of patients.[3,4,5,6,7,]

Systematic Reviews
Aleem et al (2016) reported on a meta-analysis of the efficacy of electrical stimulators for bone healing.[8,] The review was reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analyses 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 with 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 five included treatment of nonunion[9,10,11,] or delayed union[12,13,] fractures. Nonunion or delayed-union fractures were combined in subgroup analyses including 174 participants. The estimated relative risk for electrical stimulators vs 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.

Griffin et al (2008) reported on a systematic review of electromagnetic bone growth stimulation that included 49 studies, 3 of which were RCTs.[14]

The two largest and most recent trials of nonunion fractures are described in the following section.

Randomized Controlled Trials
An RCT by Scott and King (1994) compared capacitive coupled electric fields with sham treatment (dummy unit) in 23 patients who had a 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.[11] In this trial, electrodes were passed onto the skin surface through holes in the plaster cast. Twenty-one patients completed the protocol (10 treatment, 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 six of ten in the treatment group healed, while none of those in the control group healed (p=0.004).

Simonis et al (2003) compared PEMF stimulation with 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.[9] 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 using identical machines not passing current through the 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% (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 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 et al (2016) review (discussed previously) reported on a combined meta- analysis of delayed and nonunion fractures.[8] Similarly, the Griffin et al (2008) review also combined delayed and nonunion fractures.[14] Both included RCTs (n=92 patients) of delayed fractures, which are described in the following section.

Also, the portion of the evidence review on electrical stimulation for delayed unions was informed by a Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessment (1992) of the RCT by Sharrard (1990; described below), which offered the following conclusion: "…Sharrard's health outcome data do not show that noninvasive electrical bone growth stimulation delivers an advantage over placebo."[15]

Randomized Controlled Trials

Shi et al (2013) reported on a randomized sham-controlled trial that included 58 patients with delayed union of surgically reduced long bone fractures (femur, tibia, humerus, radius ulna).[12] 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 trial. 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 three of four 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 (38.7%) and controls (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 did not differ significantly between PEMF therapy patients (4.8 months; range, 2-12 months) and sham controls (4.4 months; range, 2-7 months).

In the double-blind RCT by Sharrard (1990), PEMF stimulation was compared with a sham procedure using a dummy device in 45 patients with delayed union of the tibia.[13] 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 who were taking steroids were excluded, as were patients with marked bony atrophy or hypertrophy. Fifty-one patients were recruited; 45 completed the protocol (20 treatment, 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.

Griffin et al (2011) published a Cochrane review of electromagnetic field stimulation (including 3 specifically on PEMF) for treating delayed union or nonunion of long bone fractures in adults.[16] In addition to the RCTs previously reviewed, the systematic review included a study by Barker et al (1984) that randomized 17 participants with tibial nonunion to electromagnetic field stimulation or sham treatment.[10] Thus, 4 studies (total n=125 participants) were analyzed. 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 (relative risk, 1.96; 95% CI, 0.86 to 4.48). Interpretation is limited due to the substantial clinical and statistical heterogeneity in the pooled analysis. Also, there was no reduction in pain found in two trials, and none of the studies reported functional outcomes. Reviewers concluded that electromagnetic stimulation might offer some benefit in the treatment of delayed union and nonunion but the evidence was inconclusive to inform current practice.

Section Summary: Delayed Fracture Union

Two randomized sham-controlled trials have been identified in the treatment of delayed union with PEMF. In the Sharrard (1990) trial, radiographic healing was improved at 12 weeks but there were no statistically significant differences between groups for clinical outcomes. In the Shi et al (2013) trial, only the rate of healing at an average of 4.8 months was statistically significant, and it is not clear if this was a prespecified endpoint. The time to healing was not reduced by PEMF. Additional study is needed to permit greater certainty on the effect of this technology on delayed unions.

Fresh Fracture(s)

Systematic Reviews

The Aleem et al (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 vs sham.[8] Five trials (total n=366 patients) were included.[17,18,19,20,21] 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 two largest are summarized below.

Randomized Controlled Trials

Adie et al (2011) reported on results of a multicenter, double-blind, sham-controlled, randomized trial, which evaluated 12 weeks of PEMF stimulation for acute tibial shaft fractures.[17] The endpoints examined were secondary surgical interventions, radiographic union, and patient-reported functional outcomes. Approximately 45% of patients were compliant with treatment (>6 hours daily use), and 218 (84%) of 259 patients 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 postinjury) was similar for the 2 groups (15% active vs 13% sham). A per-protocol analysis comparing patients who received the prescribed dose of PEMF stimulation with sham treatment also showed no significant differences between groups. Secondary outcomes, which included surgical intervention for any reason (29% active vs 27% sham), radiographic union at 6 months (66% active vs 71% sham), 36-Item Short-Form Health Survey Physical Component Summary scores at 12 months (44.9 active vs 48.0 sham), and the Lower Extremity Functional Scale scores at 12 months (48.9 active vs 54.3 sham), also did not differ significantly between the groups.

Hannemann et al (2014) reported on a multicenter, double-blind, randomized, sham-controlled trial (n=102) conducted in the Netherlands; they found little advantage to 6 weeks of PEMF therapy for fresh scaphoid fractures (≤5 days from injury).[20] 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 did not differ significantly between groups. The median time to clinically defined union was six weeks in both groups. The return to normal range of motion at the wrist was 12 weeks in both groups. Grip strength of the dominant hand returned to normal sooner with PEMF therapy but there was no significant difference in return of grip strength of the nondominant hand. Functional outcomes were reported in 2015.[22] 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 five follow-up time points. Each of the five domains of the EuroQol-5D as well as the EuroQoL visual analog scale was also compared at each time point. There was a single 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 was similar in the 2 groups (10 days vs 13 days; p=0.65), and the total mean quality-adjusted life years was 0.84 for PEMF and 0.85 for 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 using electrical stimulators compared with sham, but this difference was not statistically significant. No differences in functional outcomes were reported between electrical stimulators and sham.

Stress Fracture(s)

Beck et al (2008) reported on a well-conducted RCT (n=44) of capacitively coupled electric fields (OrthoPak) for healing acute tibial stress fractures.[23] 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 three 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 Fracture(s)
The evidence on the use of noninvasive electrical bone growth stimulation to treat stress fracture(s) consists of an RCT. In this well-conducted trial, there was no difference in the healing rates between the stimulation and placebo groups.

Appendicular Skeletal Surgery
A comprehensive search found two small RCTs on noninvasive electrical bone growth stimulation after orthopedic surgery. Borsalino et al (1988) reported on a randomized double-blind, sham-controlled trial of PEMF stimulation (8 h/d) in 32 patients who underwent femoral intertrochanteric osteotomy for osteoarthritis of the hip.[24] Radiographic measurements at 90 days revealed significant increases in the periosteal bone callus and trabecular bone bridging at the lateral, but not the medial, cortex. The trial lacked clinical outcomes and enrolled few patients.

The trial by Dhawan et al (2004) randomized 64 patients (144 joints with triple arthrodesis or subtalar arthrodesis) to PEMF stimulation for 12 hours a day or an untreated control condition.[25] Patients at high-risk of nonfusion (rheumatoid arthritis, diabetes, or on oral corticosteroids) were excluded from the trial. The blinded radiographic evaluation found a significant decrease in the time to union (12.2 weeks for talonavicular arthrodesis vs 17.6 weeks for controls; p=0.003; 13.1 weeks for calcaneocuboid fusion vs 17.7 weeks for controls; p=0.01). 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.

Invasive Bone Growth Stimulation
A TEC Assessment (1992) indicated that semi-invasive bone growth stimulators are no longer in wide use.[15]

An updated 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][26]). Risk factors for nonunion included smoking, diabetes, Charcot (diabetic) neuroarthropathy, steroid use, and previous nonunion. The largest case series is Lau et al(2007), who described outcomes of the foot or ankle arthrodesis in 38 high-risk patients.[27] 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 by Saxena et al (2005) described outcomes from 28 high-risk patients with arthrodesis of the foot and ankle.[28] 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 another. Five patients required additional surgery.

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 RCTs and systematic reviews of RCTs. The 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 controls. There is also evidence from two small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. 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. The relevant outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of five RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. RCTs on the 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. The 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.

Supplemental Information
Clinical Input From 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 from Blue Cross Blue Shield Association, input was received from 5 academic medical centers in 2012. Input supported the use of noninvasive electrical bone growth stimulation for the treatment of fracture nonunions or congenital pseudoarthroses of the appendicular skeleton. Input concurred that noninvasive electrical bone growth stimulation is investigational for the treatment of fresh fractures and immediate postsurgical treatment after appendicular skeletal surgery. Most reviewers considered the use of noninvasive electrical bone growth stimulation to be investigational for the treatment of delayed union, arthrodesis, or failed arthrodesis.

Practice Guidelines and Position Statements
No guidelines or statements were identified.

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

Medicare National Coverage
Noninvasive stimulators are covered by Medicare for the following indications[29,]:

- "Nonunion of long bone fractures;
- Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
- Congenital pseudarthroses…."

Invasive stimulators are covered for:

- "Nonunion of long bone fractures."

"Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days."

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in March 2019 did not identify any ongoing or unpublished trials that would likely influence this review.

References

1. Buza JA, 3rd, Einhorn T. Bone healing in 2016. Clin Cases Miner Bone Metab. May-Aug 2016;13(2):101-105. PMID 27920804
2. Bhandari M, Fong K, Sprague S, et al. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. J Bone Joint Surg Am. Aug 1 2012;94(15):e1091-1096. PMID 22854998
3. Ahl T, Andersson G, Herberts P, et al. Electrical treatment of non-united fractures. Acta Orthop Scand. Dec 1984;55(6):585-588. PMID 6335345
4. Connolly JF. Selection, evaluation and indications for electrical stimulation of ununited fractures. Clin Orthop Relat Res. Nov-Dec 1981(161):39-53. PMID 6975690
5. Connolly JF. Electrical treatment of nonunions. Its use and abuse in 100 consecutive fractures. Orthop Clin North Am. Jan 1984;15(1):89-106. PMID 6607443
6. de Haas WG, Beaupre A, Cameron H, et al. The Canadian experience with pulsed magnetic fields in the treatment of ununited tibial fractures. Clin Orthop Relat Res. Jul 1986(208):55-58. PMID 3720140
7. Sharrard WJ, Sutcliffe ML, Robson MJ, et al. The treatment of fibrous non-union of fractures by pulsing electromagnetic stimulation. J Bone Joint Surg Br. Jan 1982;64(2):189-193. PMID 6978339
8. Aleem IS, Aleem I, Evaniew N, et al. Efficacy of electrical stimulators for bone healing: a meta-analysis of randomized sham-controlled trials. Sci Rep. Aug 19 2016;6:31724. PMID 27539550
9. Simonis RB, Parnell EJ, Ray PS, et al. Electrical treatment of tibial non-union: a prospective, randomised, double-blind trial. Injury. Apr 2003;34(5):357-362. PMID 12719164
10. Barker AT, Dixon RA, Sharrard WJ, et al. Pulsed magnetic field therapy for tibial non-union. Interim results of a double-blind trial. Lancet. May 5 1984;1(8384):994-996. PMID 6143970
11. Scott G, King JB. A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. J Bone Joint Surg Am. Jun 1994;76(6):820-826. PMID 8200888
12. Shi HF, Xiong J, Chen YX, et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. BMC Musculoskelet Disord. Jan 19 2013;14:35. PMID 23331333
13. Sharrard WJ. A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. J Bone Joint Surg Br. May 1990;72(3):347-355. PMID 2187877
14. Griffin XL, Warner F, Costa M. The role of electromagnetic stimulation in the management of established non- union of long bone fractures: what is the evidence? Injury. Apr 2008;39(4):419-429. PMID 18321512
15. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation for delayed union or nonunion of fractures. TEC Assessment. 1992:Volume 7:332-351.
16. Griffin XL, Costa ML, Parsons N, et al. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. Cochrane Database Syst Rev. Apr 13 2011(4):CD008471. PMID 21491410

17. Adie S, Harris IA, Naylor JM, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. J Bone Joint Surg Am. Sep 7 2011;93(17):1569-1576. PMID 21915570
18. Faldini C, Cadossi M, Luciani D, et al. Electromagnetic bone growth stimulation in patients with femoral neck fractures treated with screws: prospective randomized double-blind study. Curr Orthop Pract. 2010;21(3):282- 287.
19. Hannemann PF, Gottgens KW, van Wely BJ, et al. The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial. J Bone Joint Surg Br. Oct 2012;94(10):1403-1408. PMID 23015569
20. Hannemann PF, van Wezenbeek MR, Kolkman KA, et al. CT scan-evaluated outcome of pulsed electromagnetic fields in the treatment of acute scaphoid fractures: a randomised, multicentre, double-blind, placebo-controlled trial. Bone Joint J. Aug 2014;96-B(8):1070-1076. PMID 25086123
21. Martinez-Rondanelli A, Martinez JP, Moncada ME, et al. Electromagnetic stimulation as coadjuvant in the healing of diaphyseal femoral fractures: a randomized controlled trial. Colomb Med (Cali). Apr-Jun 2014;45(2):67-71. PMID 25100891
22. Hannemann PF, Essers BA, Schots JP, et al. Functional outcome and cost-effectiveness of pulsed electromagnetic fields in the treatment of acute scaphoid fractures: a cost-utility analysis. BMC Musculoskelet Disord. Apr 11 2015;16:84. PMID 25880388
23. Beck BR, Matheson GO, Bergman G, et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. Am J Sports Med. Mar 2008;36(3):545-553. PMID 18055921
24. Borsalino G, Bagnacani M, Bettati E, et al. Electrical stimulation of human femoral intertrochanteric osteotomies. Double-blind study. Clin Orthop Relat Res. Dec 1988(237):256-263. PMID 3191636
25. Dhawan SK, Conti SF, Towers J, et al. The effect of pulsed electromagnetic fields on hindfoot arthrodesis: a prospective study. J Foot Ankle Surg. Mar-Apr 2004;43(2):93-96. PMID 15057855
26. Petrisor B, Lau JT. Electrical bone stimulation: an overview and its use in high risk and Charcot foot and ankle reconstructions. Foot Ankle Clin. Dec 2005;10(4):609-620, vii-viii. PMID 16297822
27. Lau JT, Stamatis ED, Myerson MS, et al. Implantable direct-current bone stimulators in high-risk and revision foot and ankle surgery: a retrospective analysis with outcome assessment. Am J Orthop (Belle Mead NJ). Jul 2007;36(7):354-357. PMID 17694182
28. Saxena A, DiDomenico LA, Widtfeldt A, et al. Implantable electrical bone stimulation for arthrodeses of the foot and ankle in high-risk patients: a multicenter study. J Foot Ankle Surg. Nov-Dec 2005;44(6):450-454. PMID 16257674
29. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Osteogenic Stimulators (150.2). 2005; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&DocID=150.2&ncd_id=150.2&ncd_version=2&basket=ncd%25253A150%25252E2%25253A2%25253AOsteogenic+Stimulators&bc=gAAAABAAAAAA&. Accessed March 21, 2019.
30. Blue Cross Blue Shield Association. Medical Policy Reference Manual, No. 7.01.07 (April 2019).

Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Previous treatment plan and response
- Initial and serial radiologic reports for the past three months
- Progress notes for the past three months
- Previous operative reports

Post Service

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
	20975	Electrical stimulation to aid bone healing; invasive (operative)
HCPCS	E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
	E0749	Osteogenesis stimulator, electrical, surgically implanted
ICD-10 Procedure	3E00XGC	Introduction of Other Therapeutic Substance into Skin and Mucous Membranes, External Approach

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
06/11/2014	New Policy Adoption BCBSA Medical Policy Adoption Replaces previously existing Blue Shield Medical Policy: • Electrical Bone Growth Stimulation	Medical Policy Committee
12/15/2014	Policy title change from Electrical Bone Growth Stimulation Policy revision with position change effective 2/15/2015	Medical Policy Committee
02/15/2015	Policy revision with position change	Medical Policy Committee
07/01/2016	Policy revision without position change	Medical Policy Committee
06/01/2017	Policy revision without position change	Medical Policy Committee
06/01/2018	Policy revision without position change	Medical Policy Committee
07/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.