Medical Policy

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(See policy history boxes for previous effective dates)

Title: Bone Growth Stimulation: Electrical Bone Growth Stimulation of the Appendicular Skeleton

Description/Background

Treatment of Delayed and Nonunion Fractures

While most acute fractures heal with appropriate treatment (immobilization, limited weight-bearing, and/or surgery), some fractures go on to a delayed union (greater than 3 months) or non-union (greater than 9 months). Individuals with delayed fracture unions might progress to non-union or may heal with prolonged care or adjunctive treatments. Electrical stimulation can be an effective adjunct to standard fracture care for delayed or non-unions.

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 capacitive coupling, pulsed electromagnetic fields, 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.

Regulatory Status

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 the FDA premarket approval (all noninvasive devices) include Physio-Stim® (Orthofix), first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for the 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 pseudarthrosis. No distinction was made between long and short bones.

The FDA has approved labeling changes for electrical bone growth stimulators that remove any time frame for the diagnosis. In September 2020, FDA considered the reclassification of noninvasive electrical bone growth stimulators from Class 3 to the lower-risk Class 2 category.[1] As of March 2024, however, the devices remain Class 3.

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

FDA product code LOF.

Medical Policy Statement

Noninvasive electrical bone growth stimulation of the appendicular skeleton is **established**. It is a useful therapeutic option when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:

Noninvasive electrical bone growth stimulation of the appendicular skeleton can be appropriate for the treatment of the following:

1. Nonunions of fractures
2. Delayed unions of fractures
3. Congenital pseudarthrosis, but only in combination with other treatments
4. Delayed healing of surgical arthrodesis

These are fractures which have demonstrated absence of progressive healing over at least a 3-month period despite appropriate care including activity restrictions and immobilization. The appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis and lower extremities. To be an appropriate treatment option **ALL** the following criteria must be satisfied:

- At least 3 months have passed since the date of fracture (or surgical arthrodesis); **and**
- Serial radiographs over the most recent 3 months demonstrate no progressive signs of healing despite appropriate immobilization and protection from weight bearing; **and**
- The individual is able and willing to comply with all weight bearing **and** immobilization restrictions; **and**
- The individual is able and willing to comply with treatment protocols; **and**
- Bone is noninfected; **and**
- Nonunion is not related/secondary to malignancy

Exclusions:

All other applications of electrical bone growth simulation, including but not limited to

- The immediate post-surgical treatment after appendicular skeletal surgery
- Stress fractures
- The treatment of acute fractures (A fracture is most commonly defined as “”acute”” during the initial 7 days after the fracture occurs.) Most acute closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.
- Implantable/(Invasive) and semi-invasive electrical bone growth stimulators are considered investigational.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

20974 E0747

Other codes (investigational, not medically necessary, etc.):

20975

Rationale

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 ELECTRICAL BONE GROWTH STIMULATION

Fracture Nonunion

Clinical Context and Therapy Purpose

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 9 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 3 to 6 months from the original injury, or simply when serial radiographs fail to show any further healing. Another is the 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).[2] 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).[3]

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).

The purpose of electrical bone growth stimulation of the appendicular skeleton in individuals 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 following **PICOs** were used to select literature to inform this review.

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

Interventions
The therapy being considered is electrical bone growth stimulation. Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. Electrical bone growth stimulation is generally managed by orthopedists and orthopedic surgeons.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation of the appendicular skeleton: conservative therapy and surgery.

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

Follow-up for the procedure would be at least 6 months or until the bone has completely healed.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

The FDA 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.[4,5,6,7,8]

Systematic Reviews

Aleem et al (2016) reported a systematic review and meta-analysis on the efficacy of electrical stimulators for bone healing.[9] 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, supplemented with hand searches of major orthopedic conference proceedings 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 treatment of nonunion[10-12] or delayed-union[13,14] 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).[15] 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 sign of progression to union within the last 3 months) of a long bone.[12] Patients with systemic bone disorders, synovial pseudoarthrosis, or fracture gap of greater than half the width of the bone were excluded. In this trial, electrodes were passed onto the skin surface through holes in the plaster cast. Twenty-one patients completed the protocol (10 treatment and 11 controls). Six months after beginning treatment, an orthopedic surgeon and a radiologist, neither of them involved in the patients' management, examined radiographs and determined that 6 of 10 in the treatment group healed, while none of those in the control group healed (p=0.004).

In 2003, Simonis et al compared pulsed electromagnetic field stimulation and placebo treatment for tibial shaft fractures ununited at least 1 year after fracture, no metal implant bridging the fracture gap, and no radiologic progression of healing in the 3 months before treatment.[10] All 34 patients received operative treatment with osteotomy and unilateral external fixator prior to randomization. Treatment was delivered by external coils. Patients were assessed monthly for 6 months, and clinical and

radiographic assessments were conducted at 6 months. Treatment was considered a failure if union was not achieved at 6 months. In the treatment group, 89% of fractures healed compared with 50% in the control group (p=0.02). While a larger percentage of smokers in the treatment group healed than compared with those in the control group, the number of smokers in each group was not comparable, and the difference in healing rates between groups was not statistically significant. The authors conclude that the available evidence supports the use of pulsed electromagnetic field therapy (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.

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

Clinical Context and Therapy Purpose
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.[3]

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.

The purpose of noninvasive electrical bone growth stimulation of the appendicular skeleton in individuals with delayed fracture union is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with delayed fracture union of the appendicular skeleton.

Interventions
The therapy being considered is noninvasive electrical bone growth stimulation.

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

Electrical bone growth stimulation is generally managed by orthopedists and orthopedic surgeons.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation of the appendicular skeleton: conservative therapy and surgery. These therapies are generally managed by orthopedists and orthopedic surgeons.

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

Follow-up for the procedure would be at least 6 months or until the bone has completely healed.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Systematic Reviews
The Aleem (2016) review (discussed previously) reported a combined meta-analysis for delayed and nonunion fractures.[9] Similarly, the Griffin (2008) review also combined delayed and nonunion fractures.[15] The 2 included RCTs (n=92 patients) of delayed fractures included in both reviews are described in the following section.

Griffin et al (2011) published a Cochrane review of electromagnetic field stimulation (including 3 specifically on pulsed electromagnetic field) for treating delayed union or nonunion of long bone fractures in adults.[16] In addition to the RCTs reviewed in the following section, 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.[11] 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 (RR, 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 2 trials, and none of the studies reported functional outcomes. Reviewers concluded that electromagnetic stimulation offer some benefit in the treatment of delayed union and nonunion.

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).[13] Delayed union was defined as a failure to heal after at least 16 weeks and not more than 9 months following surgical reduction and fixation of the fracture. Patients with fracture nonunion, defined as failure to heal after more than 9 months, were excluded from the study. Treatment with 8 hours of PEMF per day was stopped when no radiographic progression was observed over 3 months or when union was achieved, with union defined as no pain during joint stressing or during motion at the fracture site and callus bridging for 3 out of 4 cortices on blinded assessment. Three

months of treatment resulted in a slight, but not statistically significant, improvement in the rate of union between PEMF-treated patients and controls (38.7% vs. 22.2%). The success rate was significantly greater with PEMF (77.4% vs. 48.1%) after an average of 4.8 months of treatment. The time to union was significantly different between PEMF (4.8 months; range, 2-12) and sham controls (4.4 months; range, 2-7).

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.[14] Stimulators were positioned on the surface of the plaster cast. Treatment began 16 to 32 weeks after injury. Patients with fracture gaps greater than 0.5 cm after reduction, systemic disease, or taking steroids were excluded, as well as patients with marked bony atrophy or hypertrophy. Fifty-one patients were recruited, and 45 completed the protocol (20 treatment and 25 control). In the treatment group, 3 patients achieved union, 2 achieved probable union, 5 showed progression to union, and 10 showed no progress after 12 weeks. In the control group, none had united, 1 had probably united, 3 progressed toward union, and 17 showed no progress.

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. In the study by Shi et al, a PEMF treatment conducted for an average of 4.8 months led to a success rate of 77.4%. This was significantly higher than the control.

Fresh Fracture(s)

Clinical Context and Therapy Purpose
The purpose of noninvasive electrical bone growth stimulation of the appendicular skeleton in individuals with acute fractures is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with acute fractures of the appendicular skeleton.

Interventions
The therapy being considered is noninvasive electrical bone growth stimulation.

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

Electrical bone growth stimulation is generally managed by orthopedists and orthopedic surgeons.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation of the appendicular skeleton: conservative therapy

and surgery. These therapies are generally managed by orthopedists and orthopedic surgeons.

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

Follow-up for the procedure would be at least 6 months or until the bone has completely healed.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Systematic Reviews
The Aleem (2016) systematic review (described previously) also included subgroup analyses for acute fractures with the outcome of radiographic nonunion at last reported follow-up (to 12 months) for electrical stimulators versus sham.[8] Five trials (total N=366 patients) were included.[17-21] 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 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.[17] 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 2 groups (15% active; 13% sham). Per protocol analysis comparing patients who actually received the prescribed dose of pulsed electromagnetic field stimulation versus sham treatment also showed no significant difference between groups. Secondary outcomes, which included surgical intervention for any reason (29% active; 27% sham), radiographic union at 6 months (66% active; 71% sham), and the SF-36 (Short Form) Physical Component Summary (44.9 active; 48.0 sham) and Lower Extremity Functional Scales at 12 months (48.9 active; 54.3 sham), also did not differ significantly between the groups.

Hanneman et al (2014) reported a multicenter double-blind, randomized, sham-controlled trial (N=102) that found little advantage of 6 weeks of PEMF for the treatment of acute (≤5 days from injury) scaphoid fractures.[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 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 nondominant hand.

Functional outcomes were reported in 2015.[20] 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 acute 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 Fracture(s)

Clinical Context and Therapy Purpose
The purpose of noninvasive electrical bone growth stimulation of the appendicular skeleton in individuals with stress fractures is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with stress fractures of the appendicular skeleton.

Interventions
The therapy being considered is noninvasive electrical bone growth stimulation.

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

Electrical bone growth stimulation is generally managed by orthopedists and orthopedic surgeons.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation of the appendicular skeleton: conservative therapy and surgery. These therapies are generally managed by orthopedists and orthopedic surgeons.

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

Follow-up for the procedure would be at least 6 months or until the bone has completely healed.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Review of Evidence
In 2008, Beck et al reported a well-conducted RCT (n=44) of capacitively coupled electric fields (OrthoPak) for healing acute tibial stress fractures.[22] 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 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

Clinical Context and Therapy Purpose
The purpose of noninvasive electrical bone growth stimulation in individuals who have had appendicular skeletal surgery is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who have had appendicular skeletal surgery.

Interventions
The therapy being considered is noninvasive electrical bone growth stimulation.

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

Electrical bone growth stimulation is generally managed by orthopedists and orthopedic surgeons.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation for individuals who have had appendicular skeletal surgery: standard postsurgical management by an orthopedic surgeon.

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

Follow-up for the procedure would be at least 6 months or until the bone has completely healed.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Review of Evidence
A comprehensive search found 2 small randomized controlled trials on noninvasive electrical bone growth stimulation after orthopedic surgery. In 1988, Borsalino et al. reported a randomized double-blind sham-controlled trial of pulsed electromagnetic field stimulation (8 hours a day) in 32 patients who underwent femoral intertrochanteric osteotomy for osteoarthritis of the hip.[23] 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 by Dhawan 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.[24] 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.

Implantable and Semi-Invasive Bone Growth Stimulation

Clinical Context and Therapy Purpose
The purpose of implantable and semi-invasive electrical bone growth stimulation in individuals who have fracture, pseudoarthrosis, or have had surgery of the

appendicular skeleton is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations
The relevant population of interest is individuals who have fracture, pseudoarthrosis, or have had surgery of the appendicular skeleton.

Interventions
The therapy being considered is implantable or semi-invasive electrical bone growth stimulation.

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.

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.

Electrical bone growth stimulation is generally managed by orthopedists and orthopedic surgeons.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation for individuals who have fracture, pseudoarthrosis, or have had surgery of the appendicular skeleton: conservative therapy, surgery, or standard postsurgical management by an orthopedic surgeon or orthopedist.

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

Follow-up for the procedure would be at least 6 months or until the bone has completely healed.

Study Selection Criteria
Methodologically credible studies were selected using the principles described in the first indication.

Review of Evidence
A comprehensive search for implantable bone stimulators identified a small number of case series, all of which focused on foot and ankle arthrodesis in patients at high risk for nonunion (summarized in reference, Petrisor and Lau [2005][25]). 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.[26] 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.[27] 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.

Section Summary: Invasive Bone Growth Stimulation
The evidence on the use of implantable and semi-invasive electrical bone growth stimulation to treat fractures, pseudarthroses, 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 pseudarthrosis 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 union 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. RCTs on delayed union of fractures were limited by small sample size and did not show a significant difference between study groups. The evidence is sufficient to determine the effects of the technology on health outcomes.

For individuals who have acute fracture(s) 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 acute fractures. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have stress fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This well-conducted RCT found that, 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation for non delayed healing, the evidence includes 2 small RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Although the results of 1 trial suggest benefits to the bone stimulation in decreased time to union, clinical outcomes were not assessed. The evidence is insufficient to determine the effects of the technology on health outcomes.

For congenital pseudarthrosis, there is not enough literature evaluating the use of this technology due to the rarity of congenital pseudarthrosis. For delayed healing following a surgical arthrodesis, there is also limited published evidence. However, noninvasive electrical bone growth stimulation may be considered an established option for these conditions.

Invasive Electrical Bone Growth Stimulation

For individuals who have fracture, pseudarthrosis, 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.

SUPPLEMENTAL INFORMATION

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

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, BCBSA received from 5 academic medical centers while this policy was under review in 2012. The input supported use of noninvasive electrical bone growth stimulation for the treatment of fracture nonunions or congenital pseudarthrosis of the appendicular skeleton. Input agreed that noninvasive electrical bone growth stimulation is investigational for immediate post-surgical treatment after appendicular skeletal surgery and treatment of acute fractures.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic

review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

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

Government Regulations

Medicare NCD "Osteogenic Stimulators," 100-3m v.2, manual section 150.2. Last updated August 2005:

Indications and Limitations of Coverage

1. Noninvasive Stimulator
   The noninvasive stimulator device is covered *only* for the following indications: (23)
   - Nonunion of long bone fractures;
   - Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
   - Congenital pseudarthrosis;
   - Effective July 1, 1996, 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 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
   - Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
   - 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.

2. Invasive (Implantable) Stimulator
   The invasive stimulator device is covered only for the following indications:
   - Nonunion of long bone fractures;
   - Effective July 1, 1996, 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 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
   - Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
   - 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.

Nationally Non-Covered Indications

- 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.

Local:

CGS Administrators, LLC. LCD for Osteogenesis Stimulators (L33796), effective for services performed on or after 07/01/2023 revision date 01/01/2024.

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements. For the items addressed in this local coverage determination, the criteria for "reasonable and necessary", based on Social Security Act §1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

For an item to be covered by Medicare, a detailed written order (DWO) must be received by the supplier before a claim is submitted. If the supplier bills for an item addressed in this policy without first receiving the completed DWO, the item will be denied as not reasonable and necessary.

For some items in this policy to be covered by Medicare, a written order prior to delivery (WOPD) is required. Refer to the DOCUMENTATION REQUIREMENTS section of this LCD and to the NON-MEDICAL NECESSITY COVERAGE AND PAYMENT RULES section of the related Policy Article for information about WOPD prescription requirements.

A nonspinal electrical osteogenesis stimulator (E0747) is covered only if any of the following criteria are met:

1. Nonunion of a long bone fracture (see Appendices section) defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, or
2. Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery, or
3. Congenital pseudarthrosis.

Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site,

and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

A nonspinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met:

1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery (see Appendices section), or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

A spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

An ultrasonic osteogenesis stimulator (E0760) is covered only if all of the following criteria are met:

1. Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; and
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if any of the criteria above are not met.

Use of an ultrasonic osteogenic stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.

Ultrasound conductive coupling gel is covered and separately payable if an ultrasonic osteogenesis stimulator is covered.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

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

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/13	2/19/13	3/4/13	Joint policy established. This policy speaks to electrical stimulation of the spine only. This topic split out from the combined policy on bone stimulation, which included electrical stimulation of the appendicular skeleton, electrical stimulation of the spine, and ultrasound stimulation.
9/1/14	6/17/14	6/23/14	Routine maintenance. Added stress fractures to the list of exclusions. References updated.
11/1/15	8/24/15	9/14/15	Routine maintenance. Policy status unchanged.
11/1/16	9/23/16	8/26/16	Routine maintenance, updated Medicare/Medicaid information, policy status unchanged.
11/1/17	8/15/17	8/15/17	Updated CMS and Hayes information. Updated background & rationale section. Added references 1 and 8. No change in policy status.
11/1/18	8/21/18	8/21/18	Routine policy maintenance. No change in policy status.
11/1/19	8/20/19		Routine policy maintenance. No change in policy status.
11/1/20	8/18/20		Rationale reorganized, no new references. No change in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
11/1/22	8/16/22		Routine policy maintenance, no change in policy status.
3/1/23	12/20/22		Added coverage for delayed unions, congenital pseudarthrosis, delayed healing after surgical arthrodesis.
3/1/24	12/19/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
3/1/25	12/17/24		Routine maintenance (jf)

			MPS-Removal of “The safety and effectiveness of” Edits made to the inclusionary section for congruence with the Bone Growth Stimulation: Ultrasound Accelerated Fracture Healing Device policy. Added: Bone is noninfected; and Nonunion is not related/secondary to malignancy Removed: The fracture gap is 1cm or less Vendor Managed: Codes 20974 and 20975 vendor managed: NA. Northwood manages code E0747

Next Review Date: 4th Qtr. 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BONE GROWTH STIMULATION: ELECTRICAL BONE GROWTH STIMULATION OF THE APPENDICULAR SKELETON

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	See government section.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.
- Duplicate (back-up) equipment is not a covered benefit.