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Electrical Bone Growth Stimulation of the Appendicular Skeleton

Table of Contents

Related Policies (if applicable)
DME101.030: Low Intensity Pulsed Ultrasound Fracture Healing Device
SUR705.013: Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

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Coverage

Noninvasive electrical bone growth stimulation (EBGS) of the appendicular skeleton **may be considered medically necessary** for:

- Delayed unions (see **NOTE 2**) of fractures or failed arthrodesis at high-risk sites (i.e., open or segmental tibial fractures, carpal navicular fractures, 5th metatarsal fractures, distal radius fractures); OR
- Failed fusions, congenital pseudarthrosis and fracture nonunions (where there is no evidence of progression of healing for 3 or more months despite appropriate fracture care).

NOTE 1: The appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities.

NOTE 2: Delayed union is defined as a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention.

All other indications for EBGS of the appendicular skeleton, including but not limited to, the following **are considered experimental, investigational, and/or unproven**:

- Treatment of fresh fractures (<14 days); OR
- Stress fractures; OR
- Immediate postsurgical treatment after appendicular skeletal surgery.

Implantable and semi-invasive EBGS to the appendicular skeleton **are considered experimental, investigational, and/or unproven**.

Policy Guidelines

Fracture Nonunion

No consensus on the definition of fracture nonunion currently exists. (2) The U.S. Food and Drug Administration (FDA) labeling for one of the electrical stimulators included in this policy 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." This time frame is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of trial participants, many of whom were serving as their own controls. 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). 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 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."

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).

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 pseudoarthrosis, and arthrodesis.

Treatment of Delayed and Nonunion FracturesI
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.

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 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 pseudoarthrosis. 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. As of September 2020, the FDA considered the reclassification of noninvasive electrical bone growth stimulators from Class III to the lower-risk Class II category. (1) As of March 2024, however, the devices remain Class 3.

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

FDA product code LOF.

Rationale

This medical policy has been updated regularly with searches of the PubMed database. The most recent literature update was performed through March 11, 2024.

Medical policies 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 uses 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 1 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 noninvasive electrical bone growth stimulation of the appendicular skeleton in individuals with fracture nonunion 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 policy.

Populations

The relevant populations of interest is individuals with fracture nonunion 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.

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:
1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. 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. (4-8)

Systematic Reviews
Aleem et al. (2016) reported on a meta-analysis of the efficacy of electrical stimulators for bone healing. (9) 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 treatments 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 (RR) 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.

Griffin et al. (2008) reported on a systematic review of electromagnetic bone growth stimulation that included 49 studies, 3 of which were RCTs. (15)

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. (12) In this trial, electrodes were passed onto the skin surface through holes in the plaster cast. Twenty-one patients completed the protocol (10 treatments, 11 controls). Six months after patients began treatment, an orthopedic surgeon and a radiologist, neither of whom were involved in patient management, examined radiographs and determined that 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. (10) 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 non-healing 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 policy.

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.

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.

<u>Study Selection Criteria</u>
Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Systematic Reviews

The Aleem et al. (2016) review (discussed previously) reported on a combined meta-analysis of delayed and nonunion fractures. (9) Similarly, the Griffin et al. (2008) review also combined delayed and nonunion fractures. (15) Both included RCTs (N=92 patients) of delayed fractures, which 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. 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.

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). (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 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 a 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. (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 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 treatments, 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

Randomized sham-controlled trials and systematic reviews have been identified in the treatment of delayed union with PEMF. These sham-controlled randomized trials have concluded that noninvasive electrical stimulators may offer some benefit for patients with delayed fracture union.

Fresh Fracture(s)

Clinical Context and Therapy Purpose

The purpose of noninvasive electrical bone growth stimulation of the appendicular skeleton in individuals with fresh 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 policy.

Populations

The relevant population of interest is individuals with fresh 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.

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:

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

Review of Evidence

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. (9) Five trials (N=366 patients) were included. (17-21) The combined RR 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. (21) 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)

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 policy.

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.

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

Review of Evidence
Beck et al. (2008) reported on 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 three weeks, which was 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 policy.

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.

Comparators
The following therapies and practices are currently being used to make decisions about electrical bone growth stimulation for patients 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 following principles:
1. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
2. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
3. To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
4. Studies with duplicative or overlapping populations were excluded.

Review of Evidence
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 hours/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 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. (24) 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 2 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 policy.

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 a 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.

Comparators

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

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

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 Petrisor and Lau [2005] [25]). 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. (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 by Saxena et al. (2005) 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 another. Five patients required additional surgery.

Section Summary: Implantable and Semi-Invasive Bone Growth Stimulation
The evidence on the use of implantable and semi-invasive electrical bone growth stimulation to treat fractures, pseudoarthrosis, 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 or delayed fracture union who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. The relevant outcomes are symptoms, change in disease status, and functional outcomes. The United States (U.S.) Food and Drug Administration (FDA)

has approved noninvasive electrical bone growth stimulation for fracture nonunions and congenital pseudoarthrosis in the appendicular skeleton, based largely on studies with patients serving as their controls. There is 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. Sham-controlled randomized trials have also concluded that noninvasive electrical stimulators may offer some benefit for patients with delayed fracture union as well. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fresh 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 fresh fractures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

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 that the technology results in an improvement in the net health outcome.

For individuals who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, 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 that the technology results in an improvement in the net health outcome.

Implantable and Semi-Invasive Electrical Bone Growth Stimulation

For individuals who have fracture, pseudoarthrosis, 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 that the technology results in an improvement in the net health outcome.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

Medicare National Coverage

Noninvasive stimulators are covered by Medicare for the following indications (28):

- “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 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	20974, 20975
HCPCS Codes	E0747, E0749

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
09/15/2024	Document updated with literature review. Coverage unchanged. No new references added.
10/15/2023	Reviewed. No changes.

01/15/2023	Document updated with literature review. Coverage unchanged. Reference 1 and 28 added; others deleted.
07/01/2021	Reviewed. No changes.
05/01/2020	New medical document originating from SUR705.013 Electrical Bone Growth Stimulation (EBGS). Noninvasive electrical bone growth stimulation (EBGS) of the appendicular skeleton may be considered medically necessary for: 1) Delayed unions of fractures or failed arthrodesis at high-risk sites (i.e., open or segmental tibial fractures, carpal navicular fractures, 5th metatarsal fractures, distal radius); OR 2) Failed fusions, congenital pseudarthrosis and fracture nonunions (where there is no evidence of progression of healing for 3 or more months despite appropriate fracture care). All other indications for EBGS, including but not limited to the following are considered experimental, investigational, and/or unproven: 1) Treatment of fresh fractures (<14 days); OR 2) Stress fractures; OR 3) Immediate postsurgical treatment after appendicular skeletal surgery. Invasive and semi-invasive EBGS to the appendicular skeleton is considered experimental, investigational, and/or unproven.