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

**Noninvasive Electrical Bone Growth Stimulation**

For individuals who have fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration has approved noninvasive electrical bone growth stimulation for fracture nonunions and congenital pseudoarthroses in the appendicular skeleton, based largely on studies with patients serving as their own controls. There is also evidence from 2 small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. However, there are few nonsurgical options in this population, and the pre-post studies of patients with nonhealing fractures support the efficacy of the treatment. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome. For individuals who have delayed fracture union, fresh or stress fracture(s), or who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of 5 RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. RCTs on delayed union of the other types of fractures were limited by small sample sizes and did not show significant differences in outcomes between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

**Policy**

**Coding Information**

Click the links below for attachments, coding tables & instructions.

Attachment I- CPT® Coding Table
Attachment II- ICD Coding Table

**When a service may be considered medically necessary**

Noninvasive electrical bone growth stimulation may be considered *medically necessary* as treatment of fracture non-unions or congenital pseudoarthroses in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities). The diagnosis of fracture nonunion must meet ALL of the following criteria:

- At least 3 months have passed since the date of fracture;
- Serial radiographs have confirmed that no progressive signs of healing have occurred;
- The fracture gap is 1 cm or less; and
- The patient can be adequately immobilized; and
- Is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

**When a service is considered investigational**

*Investigational* applications of electrical bone growth stimulation include, but are not limited to, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, or for the treatment of fresh fractures, delayed union, arthrodesis or failed arthrodesis.

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

**Definitions**

**Fresh Fracture**

A fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care (ie, closed reduction and cast immobilization).

**Delayed Union**

Delayed union is defined as a decelerating healing process as determined by serial x-rays,
together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the index injury or the most recent intervention. In contrast, nonunion serial radiographs (described next) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as “un-united fractures.”

**Fractured Nonunion**
No consensus on the definition of fracture nonunion currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing) (Bhandari et al, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture non-unions defined non-unions as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: “A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months.” This timeframe is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures, (i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in the clinical literature.

**Background**

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

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.

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

Invasive stimulation involves the surgical implantation of a cathode at the fracture site with the production of direct current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and, although the
current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours per day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed over the skin and are worn for 6 to 8 hours per day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 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 FDA premarket approval (all noninvasive devices) include Physio-Stim® (Orthofix), first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System® (Electrobiology, now Zimmer Biomet), which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses.

No distinction was made between long and short bones. FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis.

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

**Rationale**

This evidence review was originally created in December 1995 and has been updated regularly with searches of the MEDLINE database. The most recent literature update was conducted through February 23, 2017.

**NONINVASIVE ELECTRICAL BONE GROWTH STIMULATION**

**Fracture Nonunion**

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

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

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

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

Fresh Fracture(s)

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

Stress Fracture(s)

In 2008, Beck et al reported on a well-conducted RCT (N=44) of capacitively coupled electric fields (OrthoPak) for healing acute tibial stress fractures. Patients were instructed to use the device for 15 hours each day, and usage was monitored electronically. Healing was confirmed when hopping 10 cm high for 30 seconds was accomplished without pain. Although an increase in the hours of use per day was associated with a reduction in the time to healing, there was no difference in the rate of healing between treatment and placebo. Power analysis indicated that this number of patients was sufficient to detect a difference in healing time of 3 weeks, which was considered to be a clinically significant effect. Other analyses, which suggested that electrical stimulation might be effective for the radiologic healing of more severe stress fractures, were preliminary and a beneficial effect was not observed for clinical healing.

Appendicular Skeletal Surgery
A comprehensive search found 2 small RCTs 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 h/d) in 32 patients who underwent femoral intertrochanteric osteotomy for osteoarthritis of the hip. Radiographic measurements at 90 days revealed significant increases in the periosteal bone callus and in trabecular bone bridging at the lateral, but not the medial cortex. The study is limited by the small sample size and the lack of clinical outcomes.

A 2004 trial randomized 64 patients (144 joints with triple arthrodesis or subtalar arthrodesis) to pulsed electromagnetic field stimulation for 12 hours a day or to an untreated control condition. Patients at high risk of nonfusion (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.

**Invasive Bone Growth Stimulation**

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

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 in Petrisor and Lau [2005]) 26. Risk factors for nonunion included smoking, diabetes mellitus, Charcot (diabetic) neuroarthropathy, steroid use, and previous nonunion. The largest case series (2007) described outcomes of foot or ankle arthrodesis in 38 high-risk patients. Union was observed in 65% of cases by follow-up evaluation (n=18) or chart review (n=20). Complications were reported in 16 (40%) cases, including 6 cases of deep infection and 5 cases of painful or prominent bone stimulators necessitating stimulator removal. A multicenter retrospective review (2005) described outcomes from 28 high-risk patients with arthrodesis of the foot and ankle.28 Union was reported for 24 (86%) cases at an average of 10 weeks; complications included breakage of the stimulator cables in 2 patients and hardware failure in 1 patient. Five patients required additional surgery. Prospective controlled trials are needed to evaluate this procedure.

**Summary of Evidence**

**Noninvasive Electrical Bone Growth Stimulation**

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

A search of ClinicalTrials.gov in March 2017 did not identify any ongoing or unpublished trials that would likely influence this review.

Reference Resources


Original Review Date: December 1995 Page: 11 © 2017 Blue Cross Blue Shield Association. Reproduction without prior authorization is prohibited. MPRM 7.01.07 Electrical Bone Growth Stimulation of the Appendicular Skeleton


Related Policies

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

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information
BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required for services outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update Information

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
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<tr>
<td>04/2017</td>
<td>Adopted BCBSA policy MPRM 7.01.07</td>
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<tr>
<td>10/2017</td>
<td>Updated description, updated regulatory status, updated references, added Related Policy section, added ICD-10 Q74.0 to the coding table. Policy Statement remains unchanged.</td>
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Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

Gabrielle Bercy-Roberson, MD, MPH, MBA

Date Approved

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Medical Policy Number: UM.SPSVC.11
Attachment I

CPT® Coding Table

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>The following codes will be considered as medically necessary when applicable criteria have been met.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPT®</td>
<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (nonoperative)</td>
<td>Prior Approval is required</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal applications</td>
<td>Prior Approval is required</td>
</tr>
<tr>
<td>The following codes will be denied as Not Medically Necessary, Non-Covered, Contract Exclusions or Investigational</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CPT®</td>
<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
<td>Investigational</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0749</td>
<td>Osteogenesis stimulator, electrical, surgically implanted</td>
<td>Investigational</td>
</tr>
</tbody>
</table>

Attachment II

ICD-10 Code Table

The following codes are considered medically necessary when applicable criteria is met.

<p>| ICD-10 code | Description |</p>
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Q74.0</td>
<td>Other congenital malformations of upper limb(s), including shoulder girdle(includes congenital pseudoarthrosis of clavicle)</td>
</tr>
<tr>
<td>S32.2xxK-</td>
<td>Fracture of coccyx</td>
</tr>
<tr>
<td>S32.9xxK</td>
<td>Fracture of coccyx</td>
</tr>
<tr>
<td>S42.00xK-</td>
<td>Fracture of shoulder and upper arm</td>
</tr>
<tr>
<td>S42.92xK</td>
<td>Fracture of shoulder and upper arm</td>
</tr>
<tr>
<td>S49.00xK-</td>
<td>Other and unspecified injuries of shoulder and upper arm</td>
</tr>
<tr>
<td>S49.99K</td>
<td>Other and unspecified injuries of shoulder and upper arm</td>
</tr>
<tr>
<td>S52.00xK-</td>
<td>Fracture of forearm</td>
</tr>
<tr>
<td>S52.92xN</td>
<td>Fracture of forearm</td>
</tr>
<tr>
<td>S59.00xK-</td>
<td>Other and unspecified injuries of elbow and forearm</td>
</tr>
<tr>
<td>S59.99K</td>
<td>Other and unspecified injuries of elbow and forearm</td>
</tr>
<tr>
<td>S62.00xK-</td>
<td>Fracture at wrist and hand level</td>
</tr>
<tr>
<td>S62.92xK-</td>
<td>Fracture at wrist and hand level</td>
</tr>
<tr>
<td>S72.00xK-</td>
<td>Fracture of femur</td>
</tr>
<tr>
<td>S72.92xN</td>
<td>Fracture of femur</td>
</tr>
<tr>
<td>S79.00xK-</td>
<td>Other and unspecified injuries of hip and thigh</td>
</tr>
<tr>
<td>S79.99K</td>
<td>Other and unspecified injuries of hip and thigh</td>
</tr>
<tr>
<td>S82.00xK-</td>
<td>Fracture of lower leg, including ankle</td>
</tr>
<tr>
<td>S82.92xN</td>
<td>Fracture of lower leg, including ankle</td>
</tr>
<tr>
<td>S89.00xK-</td>
<td>Other and unspecified injuries of lower leg</td>
</tr>
<tr>
<td>S89.399K</td>
<td>Other and unspecified injuries of lower leg</td>
</tr>
<tr>
<td>S92.00xK-</td>
<td>Fracture of foot and toe, except ankle</td>
</tr>
<tr>
<td>S92.919K</td>
<td>Fracture of foot and toe, except ankle</td>
</tr>
</tbody>
</table>

Fracture nonunion codes for the appendicular skeleton - 7th digit “K” is subsequent encounter for nonunion (in forearm, femur, lower leg & ankle fractures 7th digits “M” and “N” are also nonunion for certain types of open fractures - in fractures of the shoulder, humerus, wrist, hand and foot there isn’t separation of open vs. closed nonunions).