Anthem

Clinical UM Guideline

Subject: Noninvasive Electrical Bone Growth Stimulation of the Appendicular Skeleton
Guideline #: CG-DME-40
Status: Revised

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Description

This document addresses the use noninvasive electrical bone growth stimulation devices for the treatment of orthopedic and neurosurgical conditions of the appendicular skeleton. This document does not address invasive electrical bone growth stimulation of any area of the body or noninvasive electrical bone growth stimulation of the spine.

Note: Please refer to the following document for additional information related to devices used to stimulate bone growth:

- CG-DME-45 Ultrasound Bone Growth Stimulation

Clinical Indications

Medically Necessary:

I. Noninvasive electrical bone growth stimulation is considered **medically necessary** when **all** of the following criteria are met:
   A. Treatment is for either of the following:
      1. Fracture nonunion of any bone of the appendicular skeleton; **or**
      2. Congenital pseudoarthroses of any bone of the appendicular skeleton; **and**
   B. At least 45 days have passed since either of the following:
      1. The date of fracture; **or**
      2. The date of appropriate fracture care; **and**
   C. No progressive signs of healing have occurred on imaging studies (for example, bony bridging and callus formation); **and**
   D. The fracture gap is less than 1 centimeter.

II. Noninvasive electrical bone growth stimulation is considered **medically necessary** as a treatment for joint fusion secondary to failed arthrodesis of the ankle or knee.

Not Medically Necessary:

I. Noninvasive electrical bone growth stimulation of any bone of the appendicular skeleton is considered **not medically necessary** when **either** of the following contraindications is present:
   A. Draining osteomyelitis; **or**
   B. Synovial pseudoarthroses.

II. Noninvasive electrical bone growth stimulation of any bone of the appendicular skeleton is considered **not medically necessary** when the above criteria are not met, including, but not limited to treatment of **any** of the following:
   A. As an adjunct to (that is, at the time of or immediately after) bunionectomy procedures (Note: When such surgery results in nonunion, the medically necessary criteria above may apply); **or**
   B. As an adjunct to (that is, at the time of or immediately after) distraction osteogenesis procedures for any indication (for example, limb lengthening, nonunion, or tibial defects); **or**
   C. Delayed/incomplete union fractures; **or**
   D. Fresh fractures; **or**
   E. Patellar tendinopathy; **or**
   F. Pathological fractures due to bone pathology or tumor/malignancy; **or**

Feedback

G. Stress fractures.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
HCPCS	
E0747	Osteogenesis stimulator; electrical, noninvasive, other than spinal applications
ICD-10 Diagnosis	
	For diagnoses related to the appendicular skeleton, including the following:
M96.0	Pseudarthrosis after fusion or arthrodesis [ankle or knee]
Q68.3	Congenital bowing of femur
Q68.4	Congenital bowing of tibia and fibula
Q68.5	Congenital bowing of long bones of leg, unspecified
Q68.8	Other specified congenital musculoskeletal deformities
Q74.0	Other congenital malformations of upper limb(s), including shoulder girdle (includes congenital pseudarthrosis of clavicle)
S32.301K-S32.9XXK	Fracture of ilium, acetabulum, pubis, ischium, other pelvis, subsequent encounter for fracture with nonunion (code range with seventh digit K)
S42.001K-S42.92XK	Fracture of shoulder and upper arm, subsequent encounter for fracture with nonunion (code range with seventh digit K)
S52.001K-S52.92XN	Fracture of forearm, subsequent encounter for fracture with nonunion (code range with seventh digit K, M or N)
S59.001K-S59.299K	Physeal fracture of ulna and radius, subsequent encounter for fracture with nonunion (co range with seventh digit K)
S62.001K-S62.92XK	Fracture at wrist and hand level, subsequent encounter for fracture with nonunion (code range with seventh digit K)
S72.001K-S72.92XN	Fracture of femur, subsequent encounter for fracture nonunion (code range with seventh digit K, M or N)
S79.001K-S79.199K	Physeal fracture of femur, subsequent encounter for fracture nonunion (code range with seventh digit K)
S82.001K-S82.92XN	Fracture of lower leg, including ankle, subsequent encounter for nonunion (code range with seventh digit K, M or N)
S89.001K-S89.399K	Physeal fracture of tibia, fibula, subsequent encounter for nonunion (code range with seventh digit K)
S92.001K-S92.919K	Fracture of foot and toe, except ankle, subsequent encounter for fracture with nonunion (code range with seventh digit K)
T84.318A-T84.318S	Breakdown (mechanical) of other bone devices, implants and grafts
T84.498A-T84.498S	Other mechanical complication of other internal orthopedic devices, implants and grafts
Z98.1	Arthrodesis status

When services are Not Medically Necessary:
For the procedure and diagnosis codes listed above when criteria are not met or for all other non-spinal diagnoses, or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

Delayed Nonunions

A number of systematic reviews and meta-analyses of randomized controlled trials (RCTs) assessing electrical stimulation have been published in the peer-reviewed medical literature. Three of these meta-analyses suggested that there is a treatment effect from electrical stimulation on bony union (Akai, 2002; Griffin, 2008; Walker, 2007). Other meta-analyses (Mollon, 2008) did not find a statistically significant benefit of electrical stimulation on delayed union or nonunions.

In a Cochrane review and meta-analysis, Griffin and colleagues (2011) pooled data from four studies involving 125 participants to assess the effects of electromagnetic stimulation for treating delayed union or nonunion of long bone fractures in adults. Three studies evaluated the effects of pulsed electromagnetic field (PEMF) therapy and one study, capacitive coupling (CC) electric fields; most data related to nonunion of the tibia. Although all studies were blinded and placebo-controlled RCTs, each study had limitations. The primary measure of the clinical effectiveness of electromagnetic stimulation was the proportion of participants whose fractures had united at a fixed time point. The overall pooled effect size was small and not statistically significant (risk ratio, 1.96; 95% confidence interval [CI], 0.86 to 4.48; 4 trials). There was substantial clinical and statistical heterogeneity in this pooled analysis (I[2]=58%). A sensitivity analysis conducted to determine the effect of multiple follow-up time-points on the heterogeneity amongst the studies showed that the effect size remained non-significant at 24 weeks (risk ratio 1.61; 95% CI, 0.74 to 3.54; 3 trials), with similar heterogeneity (I[2]=57%). No study reported functional outcome measures. The authors concluded that though the available evidence suggests that electromagnetic stimulation may offer some benefit in the treatment of delayed union and nonunion of long bone fractures, it is inconclusive and insufficient to inform current practice. More definitive conclusions on treatment effect await further well-conducted randomized controlled trials.

Shi and colleagues (2013) conducted an RCT of PEMF as an adjunct for the management of delayed union (that is, between 16 weeks and 6 months) in 58 individuals with long-bone fractures. Clinical and radiological assessments were performed to evaluate the healing status. Treatment efficacy was assessed at 3-month intervals. At the end of the study, only the rate of healing at an average of 4.8 months with PEMF treatment was statistically significant; however, it was not clear if this was a prespecified endpoint. Participants in the PEMF group showed a higher rate of union than those in the control group after the first 3 months of treatment, but this difference failed to achieve statistical significance.

According to the U.S. Food and Drug Administration's (FDA) labeling for the various devices, electrical stimulation has not been cleared or indicated for use to enhance healing of fresh fractures that are considered to be at high risk for delayed or nonunion. Two multicenter, randomized, double-blind trials evaluating the use of electrical stimulation to accelerate healing in acute scaphoid fractures (Hannemann, 2012) or reduce the rate of surgical revision because of delayed union or nonunion in acute tibial shaft fractures (Adie, 2011) failed to demonstrate the effectiveness of PEMF stimulation for these indications. In follow-up to the 2012 pilot trial, Hannemann and colleagues (2014) found little advantage of 6 weeks of PEMF for the treatment of fresh (≤ 5 days from injury) scaphoid fractures when healing was assessed by computed tomography (CT) scans versus conventional scaphoid radiographs. Outcomes included the time to clinical and radiologic union and functional outcome at 6, 9, 12, 24, and 52 weeks. Radiologic union measured by CT was not significantly different between the two 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. This sham-controlled trial does not support a benefit for PEMF stimulation as an adjunctive treatment for fresh scaphoid fractures.

Overall, there are no well-designed RCTs on the effectiveness of noninvasive electrical stimulation for the treatment of delayed/incomplete unions, patellar tendinopathy, or stress fractures. It is uncertain whether electrical stimulation offers an additional benefit compared to standard treatment alone (cast or brace immobilization, or surgery) for these types of fractures or joint deficiency/deformity.

Fracture Nonunions

Externally used CC and PEMF stimulation results in success rates for fracture nonunion between 80% to 89% in appropriately selected individuals (Simonis, 2003). There is, however, no substantive clinical evidence to predict a specific duration of treatment when treating fracture nonunions with electrical stimulation. The location and type of fracture, risk factors of the individual, the duration of nonunion prior to treatment, and past failed bone graft or failed electrical therapy are factors that may affect the duration of electrical stimulation therapy. The medical literature, including double-blind RCTs and retrospective case series, are limited in reporting time-to-heal outcomes as measured by radiographic evidence of bone healing. For those individuals where healing outcomes were reported for long bone fracture nonunions treated with electrical stimulation, healing rates were documented within 3 months of initiation of treatment to > 1 year (AHRQ, 2005).

While electrical stimulation for the treatment of orthopedic conditions has been shown to be of benefit in the treatment of long bone and short bone fracture nonunions, it is considered as either an alternative to surgical treatment or a salvage treatment for failed surgical interventions. It should not be used as an adjunct to surgical treatment. In these cases, surgical treatment is considered the definitive therapy and an adequate period of time should be allowed for evaluation of positive results.

Hallux valgus, commonly referred to as a bunion, is a complex group of disorders consisting of a lateral deviation of the great toe, outward angulation of the metatarsal toward the other foot, separation of the heads of the first and second metatarsals, and prominent soft tissue thickening over the medial surface of the head of the first metatarsal. When conservative measures such as pads and cushions and functional foot orthotics fail to reduce the associated pain or slow the progression of the deformity, surgical correction may be indicated. The choice of surgical procedure is based on a biomechanical and radiographic examination of the foot. A bunionectomy procedure (such as an Akin, Chevron, Keller, Lapidus, or Mitchell metatarsal osteotomy) may be performed to correct a symptomatic hallux valgus by reconstructing the bones and joint to restore normal, pain-free function. The most common bunionectomy procedure performed is the first metatarsal neck osteotomy, which involves a controlled 'surgical fracture' of the bone by cutting and realigning the first metatarsal near the level of the joint; additional procedures may involve soft tissue correction along with concomitant bony correction. Complications following a bunionectomy procedure vary depending on the surgical technique and procedure, including, but are not limited to delayed healing of the incision, osseous malunion or nonunion, osteomyelitis, or avascular necrosis. The peer-reviewed medical literature includes prospective, comparative and evaluation studies and retrospective case series reporting low postsurgical complication rates following specific osteotomy procedures for hallux valgus (Dennis, 2011; Enan, 2010; Lee, 2010; Miller, 2011). While there is a lack of published RCTs comparing the efficacy of electrical bone growth stimulation to sham treatment for postsurgical bunionectomy nonunion, the stimulation device may be a treatment option for individuals to reduce the need for further surgical revision when the individual's osteotomy site has demonstrated no evidence of progression of healing.

No studies were identified in the peer-reviewed literature specifically focused on improved healing rates following uncomplicated bunionectomy procedures (first metatarsal osteotomy) as compared to a period of immobilization and limited weight bearing; in addition, these surgeries are not considered at high risk for post-surgical nonunion.

Arthrodesis of the Ankle or Knee

The use of noninvasive electrical stimulation has been studied as an adjunct treatment for joint fusion secondary to failed arthrodesis of the ankle and knee. While the evidence for this application is not extensive, there are several reports that illustrate the usefulness of this therapy. In this situation, the initial joint fusion should be considered the definitive treatment for these types of fractures. In the event that this treatment fails, it may be appropriate to apply electrical stimulation immediately following the revision procedure. The level of evidence to support this conclusion is reported in multiple case series in the medical literature.

Distraction Osteogenesis

There is a lack of large RCTs to support the use of PEMF for enhancing bone formation in distraction osteogenesis (DO) following limb-lengthening procedures. Eyres (1996) published a small RCT with 13 individuals who underwent limb lengthening during DO. The trial did not find significant differences in the rate or amount of new bone formation in participants who received treatment from an active PEMF coil compared with sham coil treatment. Luna Gonzalez and colleagues (2005) evaluated a small group of adolescents (n=30) of short stature who underwent bilateral humeral lengthening. At Day 10 after surgery, PEMF stimulation was started on one side, for 8 hours/day. The extremity managed with PEMF was reported as exhibiting faster callus formation and greater bone density then did the contralateral control side.

Other Considerations

Definitive selection criteria of candidates for noninvasive electrical bone growth stimulation have not been firmly established. However, there is sufficient evidence to conclude that this technology can provide benefit for individuals with persistent long bone nonunions. The product label of the Physio-Stim® bone growth stimulator (Orthofix Inc., Lewisville, TX) states that the device:

> …is indicated for the treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones, where the width of the nonunion defect is less than one-half the width of the bone to be treated. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

The FDA premarket approval (PMA) applications for noninvasive electrical bone growth stimulation devices contain information on the safety and effectiveness of these devices. These summaries state the devices are contraindicated in individuals lacking skeletal maturity, individuals with a demand-type pacemaker or implantable cardioverter defibrillator

(ICD), and pregnant women. Although indications vary among devices, the safety and effectiveness of electrical bone growth stimulation has not been established with a nonunion secondary to or in connection with a pathological condition, is not indicated for misaligned fracture nonunion, when a synovial pseudarthrosis exists, when the bone gap is ≥ 1 centimeter or > ½ the diameter of the bone, and for individuals who are unable to be compliant with the appropriate use of a noninvasive device and treatment regimens.

Definitions

Appendicular skeleton: Composed of bones of the upper and lower limbs, and the bones that anchor the upper and lower limbs to the axial skeleton:

- upper extremities (humerus, radius, ulna, carpal, metacarpal, and phalange bones)
- lower extremities (femur, tibia, fibula, patella, tarsal, metatarsal, and phalange bones)
- shoulder or pectoral girdle (clavicle and scapula bones)
- pelvic or hip girdle

Bunionectomy: A surgical procedure to remove a bony bump (bunion) of the foot and realign the big toe (great toe).

Delayed/incomplete fracture union: A fracture that has not healed within the expected timeframe for the site and type of fracture in a given individual despite ongoing bone growth activity; demonstrated by slow radiographic progress and continued mobility and pain at the fracture site.

Distraction osteogenesis (DO): A procedure that moves two segments of a bone slowly apart in such a way that new bone fills in the gap.

Electrical bone growth stimulator: A medical device that uses an electric field or current to stimulate the growth of bone tissue. These devices may be worn on the outside of the body or can be surgically implanted around the area requiring treatment.

Fracture nonunion: A fracture in which all evidence of bone growth activity at the fracture site has ceased, leaving a persistent unhealed fracture of the bone.

Fracture union: The point at which the fractured bone has regained sufficient strength and stiffness to function as a weight-bearing structure without external support.

Hallux valgus deformity (bunion): A medial deviation of the first metatarsal and lateral deviation and/or rotation of the hallux, with or without medial soft-tissue enlargement of the first metatarsal head. This condition can lead to painful motion of the joint or difficulty with footwear.

Irregular bones: Bones that are irregular in size and shape and are usually quite compact; include the bones in the vertebral column, the carpal bones in the hands, tarsal bones in the feet, and the patella (kneecap).

Long bones: Bones found in the extremities comprised of a shaft (diaphysis) and 2 ends (epiphyses); includes the humerus, radius, ulna, femur, tibia, fibula, metatarsal, and metacarpal bones.

Osteotomy: A surgical procedure where a bone or segment of a bone is cut or removed, realigned, and allowed to heal in its new position; most often, performed to realign a deformed bone.

Pseudoarthrosis: A condition where a bone fracture has healed with fibrous material instead of bone tissue; referred to as pseudarthrosis or a “false joint.”

Sesamoid bones: An ovoid, nodular mass of bone or cartilage within a tendon or joint capsule, principally in the hands and lower extremities; the patella is the largest sesamoid bone in the body.

Short bones: Bones with a tubular shaft and articular surfaces at each end but much smaller in size; includes all of the metacarpals and phalanges in the hands, the metatarsals and phalanges in the feet, and the clavicle (collarbone).

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The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Revised	02/20/2025	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised formatting in the Clinical Indications section. Revised Definitions, References and Websites for Additional Information sections.
Reviewed	02/15/2024	MPTAC review. Revised References and Websites for Additional Information sections.
Revised	02/16/2023	MPTAC review. Revised formatting and made minor language revisions to MN and NMN criteria. Updated References and Websites for Additional Information sections.
Reviewed	11/10/2022	MPTAC review. Updated Discussion/General Information, References and Websites sections.
Reviewed	11/11/2021	MPTAC review. Updated References and Websites sections.
Reviewed	11/05/2020	MPTAC review. References and Websites sections updated. Reformatted Coding section.
Reviewed	11/07/2019	MPTAC review. Description, Discussion/General Information and References sections updated.
Revised	11/08/2018	MPTAC review. Revised document to only address noninvasive electrical bone growth stimulation of the appendicular skeleton (removed information related to invasive and semi-invasive electrical bone growth stimulation for all conditions and noninvasive bone growth stimulation for spinal conditions). Title changed to Noninvasive Electrical Bone Growth Stimulation of the Appendicular Skeleton. Updated Coding section to

		remove codes 20975, E0749 and ICD-10-PCS codes for invasive procedures, and E0748 and diagnosis codes for spinal indications for noninvasive procedures.
New	11/02/2017	MPTAC review. Initial document development. Moved content of DME.00004 to new clinical utilization management guideline document with the same title.

Federal and State law, as well as contract language, and Medical Policy take precedence over Clinical UM Guidelines. We reserve the right to review and update Clinical UM Guidelines periodically. Clinical guidelines approved by the Medical Policy & Technology Assessment Committee are available for general adoption by plans or lines of business for consistent review of the medical necessity of services related to the clinical guideline when the plan performs utilization review for the subject. Due to variances in utilization patterns, each plan may choose whether to adopt a particular Clinical UM Guideline. To determine if review is required for this Clinical UM Guideline, please contact the customer service number on the member's card.

Alternatively, commercial or FEP plans or lines of business which determine there is not a need to adopt the guideline to review services generally across all providers delivering services to Plan’s or line of business’s members may instead use the clinical guideline for provider education and/or to review the medical necessity of services for any provider who has been notified that his/her/its claims will be reviewed for medical necessity due to billing practices or claims that are not consistent with other providers, in terms of frequency or in some other manner.

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