Regence

**Medical Policy Manual** Durable Medical Equipment, Policy No. 83.11

# *Electrical Bone Growth Stimulators (Osteogenic Stimulation)*

**Effective**: October 1, 2023

**Next Review:** August 2024
**Last Review:** August 2023

## IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

## DESCRIPTION

Electrical bone growth stimulators (EBGS) are devices that use electrical currents to promote bone growth and healing. Three types of EBGS are available: invasive, non-invasive and semi-invasive.

## MEDICAL POLICY CRITERIA

I. **Noninvasive** electrical bone growth stimulation may be considered **medically necessary** when all of the following Criteria (A.- C.) are met:

A. Patient is skeletally mature (see Policy Guidelines); and

B. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to stimulation; and

C. One or more of the following Criteria is met:

1. As an adjunct to spinal fusion surgery when clinical records document one or more of the following risk factors for failed fusion:

a. One or more previous failed spinal fusion(s), defined as a spinal fusion which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months; or

b. Grade III or worse spondylolisthesis; or

c. Lumbar fusion performed at two or more levels; or

d. Cervical fusion performed at three or more levels; or

e. Uncontrolled diabetes, defined as HbA1c ≥ 8%; or

f. Clinical documentation of chronic kidney disease, defined as CKD stage 3 or 4; or

g. Significant osteoporosis, defined as T score <-2.5; or

h. Systemic steroid use (e.g. daily dose ≥5 mg prednisone or equivalent for ≥ three months) associated with low bone mass or bone loss; or

2. Treatment for any of the following conditions:

a. Failed spinal fusion defined as a spinal fusion which has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months; or

b. Congenital pseudoarthroses; or

c. Fracture nonunions meeting all of the following criteria:

i. Location in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities); and

ii. At least 3 months have passed since the date of fracture or most recent open reduction; and

iii. Serial radiographs have confirmed that no progressive signs of healing have occurred over the most recent 3-month period following fracture or open reduction; and

iv. The fracture gap is 1 cm or less; and

v. The patient can be adequately immobilized.

II. **Invasive** electrical bone growth stimulation may be considered **medically necessary** as an adjunct to spinal fusion surgery when all of the following Criteria (A.-C.) are met:

A. Patient is skeletally mature (see Policy Guidelines); and

B. The patient is not a tobacco user OR there is clinical documentation that the patient has been abstinent from tobacco use for at least six weeks prior to stimulation; and

C. Clinical records document at least one of the risk factors in Criterion I.C.1.

III. The replacement of all or part of an existing stimulator and/or generator is considered **medically necessary** when the existing stimulator and/or generator is malfunctioning, cannot be repaired, and is no longer under warranty.

IV. Revision(s) to an existing osteogenic stimulator may be considered **medically**

**necessary** after the device has been placed.

V. Replacement of all or part of an existing stimulator is considered **not medically necessary** when Criterion III. is not met.

VI. Invasive or noninvasive electrical bone growth stimulation is considered **not medically necessary** for any of the following:

   A. When Criterion I. or II. is not met;

   B. As an adjunct to spinal fusion performed in the absence of any other risk factor(s) for failed spinal fusion (see I.C.1.[a. - h.] for risk factors);

   C. Fresh fractures (defined as receiving treatment within 14 days of injury or open reduction);

   D. Stress fractures (defined as a fatigue-induced fracture resulting from repeated stress over time), stress reaction, or bone marrow edema;

   E. Acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis;

   F. Failed (non-spinal) joint fusion following arthrodesis. Failed joint fusion following arthrodesis is defined as a joint fusion which has not healed at a minimum of 6 months after the arthrodesis, as evidenced by serial x-rays over a course of 3 months;

   G. Osteonecrosis, defined as Osteonecrosis, defined as loss of blood flow to bone tissue, which causes the bone to die;

   H. Osteotomy.

VII. Invasive or noninvasive electrical bone growth stimulation is considered **investigational** for the treatment of all other conditions not addressed in Criterion I. and II.

VIII. Semi-invasive electrical bone growth stimulation is considered **investigational** for the treatment of all conditions.

*NOTE: A summary of the supporting rationale for the policy criteria is at the end of the policy.*

## POLICY GUIDELINES

Skeletally mature refers to a system of fused skeletal bones, which occurs when bone growth ceases after puberty; for females, this generally occurs around age 16, and for males, around age 18.

## LIST OF INFORMATION NEEDED FOR REVIEW

It is critical that the list of information below is submitted for review to determine if the policy criteria are met. If any of these items are not submitted, it could impact our review and decision outcome.

1. History and Physical/Chart notes documenting policy criteria are met including documentation supporting skeletal maturity and non-tobacco status of the patient.

2. Failed Spinal Fusion: six months post-operative failure to heal, serial X-ray over three months
3. Documentation of congenital pseudoarthroses if applicable.
4. Nonunions: Nonunion documentation of location, three months post op, serial radiographs documenting no progressive signs of healing over three months, fracture gap measurement, documented compliance with immobilization.
5. Invasive EBGS: documentation the EBGS is an adjunct to spinal fusion surgery with documentation supporting risk factors consistent with policy criteria.
6. Noninvasive EBGS: documentation of adjunct to spinal fusion surgery with documentation supporting risk factors consistent with policy criteria.

## CROSS REFERENCES

1. Lumbar Spinal Fusion, Surgery, Policy No. 187
2. Ultrasonic Bone Growth Stimulators (Osteogenic Stimulation), Durable Medical Equipment, Policy No. 83.12
3. Electromagnetic Therapy, Durable Medical Equipment, Policy No. 83.13

## BACKGROUND

Electrical bone growth stimulators (EBGS) are devices that use electrical currents to promote bone growth and healing. Three types of EBGS are available:

- Noninvasive EBGS

  Noninvasive EBGS are externally worn devices that generate a weak electric current within the target site using either pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. The electrodes are usually placed on the skin and, depending on the technology, worn from 30 minutes to 24 hours per day until healing occurs (up to 9 months).

- Invasive EBGS

  Invasive EBGS use direct current and require surgical implantation of both the current generator and an electrode. Usually, the generator is implanted in an intramuscular or subcutaneous space, and an electrode is implanted within the target bone site. The device typically remains functional for 6 to 9 months after implantation. Upon completion of treatment, the generator is removed in a second surgical procedure. The electrode may or may not be removed.

- Semi-invasive EBGS

  Semi-invasive (semi-implantable) EBGS use direct current supplied by an external power generator and percutaneously placed electrodes.

### REGULATORY STATUS

A number of bone growth stimulators from several manufacturers have received premarket approval from the U.S. Food and Drug Administration (FDA).

### BONE FRACTURES

An estimated 7.9 million fractures occur annually in the United States. Most bone fractures heal spontaneously over several months following standard fracture care (closed reduction if necessary, followed by immobilization with casting or splinting). However, approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services.[1] 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).[2]

### FRESH (ACUTE) FRACTURE

While there is no standard definition of a "fresh" fracture, the most common definition is within seven days after the fracture occurs.[3, 4] Other studies have defined fresh as less than five days after fracture and as up to 10 days postfracture, and other studies have suggested even more variable timeframes based on fracture location.[5] Most fresh closed fractures heal without complications using of standard fracture care (i.e., closed reduction and cast immobilization).

### FRACTURE NONUNION

There is no consensus on the definition of nonunions applicable to all fractures, given variations in the bone tissue and fracture characteristics.[2] A 2005 AHRQ Technology Assessment review found that nonunion is most commonly defined as the absence of signs of healing for an additional three months after assessment is made that healing is delayed.[6] These definitions do not reflect the underlying conditions in fractures that affect healing, such as the degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock. There also is variability in the specific radiographic and clinical criteria used to diagnose nonunion. A review of the literature found that 79% of surgeons use radiographic evidence of cortical continuity as the primary means of defining fracture nonunion, and 42% also used weight-bearing and 37% used pain at the fracture site during palpation.[7]

## EVIDENCE SUMMARY

Evidence from randomized controlled trials (RCTs) is needed to establish safety and efficacy of electrical bone growth stimulators (EBGS) as a treatment for any indication.

Despite the lack of reliable evidence, both invasive and noninvasive EBGS have evolved into a standard of care for certain conditions. The focus of this summary is on the uses of EBGS that are considered investigational.

### NONINVASIVE EBGS AS AN ADJUNCT TO SPINAL FUSION

Coric (2018) published results from an industry-sponsored multicenter cohort study of pulsed electromagnetic field (PEMF) treatment in patients at high-risk of cervical arthrodesis following anterior cervical discectomy and fusion procedures. The trial described results using the Cervical-Stim device (Orthofix) for 274 patients enrolled across three institutions. All patients had one or more risk factors, defined as nicotine user, osteoporosis, diabetes, age greater than 65 years or greater than 50 years, for pseudoarthrosis, and were treated with PEMF stimulation for three to six months. A historical control group was generated from a post hoc analysis of high-risk subjects from the original Food and Drug Administration (FDA) investigational device exemption trial. The primary endpoint was bone fusion rates as assessed at six and 12 months by the treating surgeon not blinded to clinical symptoms and outcomes for subjects. At six months, statistically significant improvements in fusion rates

were found for patients falling into the following risk factor groups; age over 50 years and 2-level arthrodesis (p=0.002); age over 50 years and 3-level arthrodesis (p<0.001); age over 65 years and 2- level arthrodesis (p=0.009); and age over 65 years and 3-level arthrodesis (p=0.002). Likewise, at 12 months, statistically significant improvements in fusion rates were found for patients falling into the following risk factor groups; age over 50 years and 2-level arthrodesis (p=0.002); age over 50 years and 3-level arthrodesis (p<0.001); age over 65 years and 2-level arthrodesis (p=0.001); and age over 65 years and 3-level arthrodesis (p<0.001). Study limitations included the use of a historical control group from the original investigational device exemption trial instead of a prospective control group, surgeons who were not blinded to clinical symptoms and outcomes, and surgeons who were not restricted as to the surgical procedures used during the study.

In 2008, Foley published results of the industry-sponsored investigational device exemption (IDE) study of PEMF stimulation as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants.[8, 9] This study described results using the Cervical-Stim device from Orthofix that received premarket approval (PMA) from the FDA in 2004. A total of 323 patients were randomized, 163 to PEMF and 160 to no stimulation. All patients were active smokers (more than one pack of cigarettes per day, 164 patients) or were undergoing multilevel ACDF (192 patients). Patients with pertinent history of trauma, previous posterior cervical approach or revision surgery, and certain systemic conditions or steroid use, and regional conditions such as Paget's disease or spondylitis were excluded. Beginning one week after surgery, patients in the treatment group wore the Cervical-Stim device for 4 hours per day for three months.

Efficacy was measured by radiographic analysis at one, two, three, six, and 12 months. At six months, 122 patients in the treatment group and 118 in the control group were evaluable; 15 in the PEMF group and 13 in the control group voluntarily withdrew, seven in the PEMF group and one control violated study protocol, and 19 in the PEMF group and 28 controls had radiographs that were not evaluable or radiographs that were not done within two weeks of the six-month postoperative window. Fusion rates for the 240 (74%) evaluable patients at six months were 83.6% for the PEMF group and 68.6% for the control group (p=0.0065). By intent-to-treat (ITT) analysis, assuming that nonevaluable patients did not have fusion, PEMF and control groups fusion rates were 65.6% and 56.3%, respectively; these rates were not significantly different (p=0.0835). (FDA analysis, however, indicated that the results at 6 months were still statistically different in sensitivity analysis performed with the last observation carried forward or with all missing data imputed as nonfusion.) Of 245 patients available for follow-up at 12 months, fusion was achieved in 116 of 125 (92.8%) PEMF patients and 104 of 120 (86.7%) control patients; these rates were not significantly different (p=0.1129). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not included in the paper.

Clinical outcomes were not reported in the 2008 publication but were reported to the FDA. With clinical success defined as no worsening in neurologic function, an improvement in visual analogue scale (VAS) pain assessment, and no worsening in Neck Disability Index, the study found no significant difference between groups in the percent of subjects considered a clinical success at 6 months (p=0.85) or 12 months (p=0.11). The marginal difference in fusion rates by ITT analysis at six months, nonsignificant difference in fusion rates at 12 months, and lack of difference in functional outcomes at either six or 12 months do not support the efficacy of this device as an adjunct to anterior cervical fusion.

Due to the methodologic limitations in the only controlled trial published to date, the efficacy of electrical stimulation as an adjunct to cervical spinal fusion performed at more than two levels, in patients with risk factors, has not been established. In addition, requests for EBGS as an adjunct to spinal fusion surgery may be requested in the postoperative setting only because surgery may be delayed indefinitely or cancelled in higher risk patients.

## OTHER INDICATIONS FOR NONINVASIVE EBGS

### Fresh/Acute Fractures

Systematic Review

Aleem (2016) published a systematic review (SR) which included subgroup analyses for fresh fractures with the outcome of radiographic nonunion at last reported follow-up (to 12 months) for electrical stimulators versus sham.[10] Five trials (total N=366 patients) were included. The combined relative risk of radiographic nonunion was 0.83 (95% CI, 0.51 to 1.35; I2=11%; p=0.35). The selected trials were of moderate-to-high quality. The two largest are summarized below.

Randomized Controlled Trials

Adie (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.[11] 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 (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).[12] Outcomes included the time to clinical and radiologic union and functional outcome at six, nine, 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 6 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 also were reported in 2015.[13] There were no significant differences in either the pain or the function subscales of the Patient-Rated Hand/Wrist Evaluation between the PEMF group and the sham group at any of the 5 follow-up time points. Each of the 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 two 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.

### Stress Fractures

Randomized Controlled Trial (RCT)

In 2008, Beck reported a well-conducted randomized controlled trial (n=44) of capacitively coupled electric field stimulation for healing acute tibial stress fractures.[14] 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. Power analysis indicated that this number of patients was sufficient to detect a difference in healing time of three weeks, which was considered to be a clinically significant effect. No difference was detected in the rate of healing between treatment and placebo groups.

## INVASIVE EBGS (EXCEPT AS AN ADJUNCT TO SPINAL FUSION SURGERY)

### Technology Assessments

The 1992 BlueCross BlueShield Association (BCBSA) Technology Evaluation Center (TEC) assessment of invasive EBGS for the treatment of delayed union or nonunion in long bones was based on a case series of 84 patients, the only published study on the topic at the time.[4] The assessment concluded that "the evidence does not permit conclusions about whether health outcomes are improved, for either nonunion or delayed union" as a result of EBGS therapy.

### Randomized Controlled Trials

There are no published randomized controlled trials (RCTs) on the use of invasive EBGS for any indications other than as an adjunct to spinal fusion surgery.

### Nonrandomized Studies

Two small observational studies reported experiences of patients at high risk for nonunion who received invasive EBGS to enhance the foot and ankle arthrodeses.[15, 16] While these studies contribute to the body of knowledge by providing direction for future research, evidence from these studies is unreliable due to significant design flaws, such as non-random allocation of treatment and lack of (adequate) comparison groups.

## SEMI-INVASIVE EBGS

Semi-invasive EBGS is no longer in wide use. Consequently, there are no recently published studies of semi-invasive EBGS for the treatment of any condition.

# PRACTICE GUIDELINE SUMMARY

Currently, there are no published, evidence-based guidelines which recommend the use of electrical bone growth stimulation for the treatment of any condition, except as an adjunct to spinal fusion surgery.

## NORTH AMERICAN SPINE SOCIETY

In 2016, the North American Spine Society issued a coverage recommendation for electrical bone growth stimulators, which stated the following:[12]

1. For augmentation of spinal fusion in any and all regions of the spine including occipital-cervical, cervical, cervicothoracic, thoracic, thoracolumbar, lumbar and lumbosacral spinal regions in patients at high-risk for the development of pseudarthrosis (ie, nonunion) who exhibit one or more of the following:
    a. Are undergoing spinal fusion of two or more motion segments (3 vertebrae)
    b. Are undergoing a revision spinal fusion (eg, repeat surgery for a previously unhealed fusion attempt)
    c. Are smokers who cannot stop smoking in preparation for fusion due to the nature of the underlying condition (e.g., acute traumatic fracture)
    d. Exhibit one or more of the following comorbidities when undergoing primary lumbar fusion:
        i. Diabetes
        ii. Inflammatory arthritis (eg, rheumatoid arthritis) that has required long-term corticosteroid therapy
        iii. Immunocompromised (eg, undergoing chemotherapy and radiation therapy to the spine, hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease)
        iv. Systemic vascular disease
        v. Osteopenia or osteoporosis
2. In the lumbar spine, the following forms of electrical stimulation are indicated in high-risk patients with the specific techniques outlined. In all other regions of the spine, coverage for the same indications is recommended although there is less supporting evidence.
    a. DCS [direct current stimulation: electrodes implanted within or very close to the location of the desired fusion] and CCS [capacitance coupling stimulation; 2 electrodes placed on the skin over the fusion site] for posterolateral fusion using autograft and extender
    b. PEMFS [pulsed electromagnetic field stimulation: coils that produce a time-varying magnetic field around the area of the desired [fusion] for lumbar interbody fusion.

## AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS (AANS) AND THE CONGRESS OF NEUROLOGICAL SURGEONS (CNS)[17, 18]

Updated 2014 guidelines from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) state that there is no evidence published after their 2005 guidelines that conflicts with the previous recommendations regarding bone growth stimulation.[18] Based on a single level II study from 2009, the routine use of direct current stimulation (DCS) in patients older than age 60 years was not recommended. Use of DCS was recommended as an option for patients younger than 60 years of age, based on level III and IV studies showing a positive impact on fusion rate. However, comments regarding the level III study were that it was a poorly designed and poorly conducted cohort study consisting of an exceedingly small heterogeneous population of patients, and the overall recommendation was level C. There was insufficient evidence to recommend for or against the use of pulsed electromagnetic field stimulation (PEMFS) as a treatment alternative to revision surgery in patients presenting with pseudoarthrosis following posterolateral lumbar fusion

(PLF; single-level IV study). No additional studies investigating the efficacy of capacitively coupled electrical stimulation were identified.

The 2005 AANS/CNS guideline stated that there is class II and III evidence (nonrandomized comparative trials and case series) "…to support the use of direct current stimulation or [capacitative coupled stimulation] for enhancing fusion rates in high-risk patients undergoing lumbar PLF. A beneficial effect on fusion rates in patients not at "high risk" has not been convincingly demonstrated, nor has an effect been shown for these modalities in patients treated with interbody fusion. There is limited evidence both for and against the use of PEMFS for enhancing fusion rates following PLF. Class II and III medical evidence supports the use of PEMFS for promoting arthrodesis following interbody fusion. Although some studies have purported to demonstrate functional improvement in some patient subgroups, other studies have not detected differences. All of the reviewed studies are significantly flawed by the use of a four-point patient satisfaction scale as the primary outcome measure. This outcome measure is not validated. Because of the use of this flawed outcome measure and because of the conflicting results reported in the better-designed studies that assess functional outcome, there is no consistent medical evidence to support or refute use of these devices for improving patient outcomes.

## SUMMARY

### NONINVASIVE ELECTRICAL BONE GROWTH STIMULATION (EBGS)

#### As an Adjunct to Spinal Fusion Surgery

There is enough research to show that using noninvasive electrical bone growth stimulation (EBGS) as an adjunct to spinal fusion leads to higher fusion rates in small subsets of patients that exhibit certain risk factors for failed fusion. Therefore, invasive EBGS may be considered medically necessary as an adjunct to spinal fusion surgery when policy criteria are met.

There is not sufficient evidence that noninvasive electrical bone growth stimulation improves health outcomes as an adjunct to spinal fusion when spinal fusion is performed in the absence of any risk factor(s). In addition, evidence-based clinical practice guidelines do not recommend electrical bone growth stimulation as an adjunct to spinal fusion when spinal fusion is performed in the absence of any risk factor(s). Therefore, the use of noninvasive electrical bone growth stimulation as an adjunct to spinal fusion is considered not medically necessary when spinal fusion is performed in the absence of any risk factor(s) for failed spinal fusion and when policy Criteria are not met.

#### Non-Spine Indications

There is enough research to show that noninvasive electrical stimulation improves fracture healing for certain patients with fracture nonunion. In addition, the U.S. Food and Drug Administration has approved noninvasive electrical bone growth stimulators for fracture nonunions and congenital pseudoarthroses, and it is acknowledged that there are limited other options in these populations. Therefore, noninvasive electrical bone growth stimulators may be considered medically necessary for fracture nonunion when policy criteria are met.

In addition, noninvasive electrical bone growth stimulators may be considered medically necessary for congenital pseudoarthroses.

There is evidence to show that noninvasive electrical bone growth stimulators do not improve health outcomes for fracture nonunion in certain situations. Evidence-based clinical practice guidelines do not recommend noninvasive electrical bone growth stimulation for conditions not meeting Criteria. Therefore, noninvasive electrical bone growth stimulators are considered not medically necessary when Criteria are not met.

### Fresh and Stress Fractures

Properly controlled trials have failed to find an added benefit of noninvasive electrical bone growth stimulators to health outcomes in patients with stress or fresh fractures. Evidence-based clinical practice guidelines recommending the use of electrical bone growth stimulation in the appendicular skeleton were not identified. Therefore, the use of noninvasive electrical bone growth stimulators for the treatment of stress or fresh fractures is considered not medically necessary.

### Other Indications

There is not sufficient evidence that noninvasive electrical bone growth stimulation improves health outcomes for acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis, failed joint fusion following arthrodesis, osteotomy, or for the treatment of osteonecrosis. Evidence-based clinical practice guidelines recommending the use of noninvasive bone growth stimulation in these conditions were not identified. Therefore, noninvasive electrical bone growth stimulation is considered not medically necessary for acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis, failed joint fusion following arthrodesis, osteotomy, or for the treatment of osteonecrosis.

Due to a lack of research, noninvasive electrical bone growth stimulation (EBGS) is considered investigational for the treatment of all other conditions.

## INVASIVE ELECTRICAL BONE GROWTH STIMULATION

### As an Adjunct to Spinal Fusion Surgery

There is enough research to show that using invasive electrical bone growth stimulation (EBGS) as an adjunct to spinal fusion leads to higher fusion rates in patients that exhibit certain risk factors for failed fusion. In addition, there are clinical practice guidelines that recommend the use of invasive EBGS for patients with risk factors for failed spinal fusion. Therefore, invasive EBGS may be considered medically necessary as an adjunct to spinal fusion surgery when policy criteria are met.

There is not enough evidence that invasive electrical bone growth stimulation improves health outcomes as an adjunct to spinal fusion when spinal fusion is performed in the absence of any risk factor(s). In addition, clinical practice guidelines do not recommend invasive electrical bone growth stimulation as an adjunct to spinal fusion when spinal fusion is performed in the absence of any risk factor(s). Therefore, the use of invasive electrical

bone growth stimulation as an adjunct to spinal fusion is considered not medically necessary policy criteria are not met.

**Spine and Non-Spine Indications**

There is not sufficient evidence that invasive electrical bone growth stimulation improves health outcomes for the treatment of fresh fracture(s), delayed union, stress fracture(s), osteotomy, osteonecrosis, acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis, or failed joint fusion following arthrodesis. In addition, no evidence-based clinical practice guidelines recommend invasive electrical bone growth stimulation for these indications. Therefore, the use of invasive electrical bone growth stimulation for the treatment of fresh fracture(s), delayed union, stress fracture(s), acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis, or failed joint fusion following arthrodesis is considered not medically necessary.

Due to a lack of research, invasive electrical bone growth stimulation is considered investigational for the treatment of all other conditions.

**SEMI-INVASIVE ELECTRICAL BONE GROWTH STIMULATION (EBGS)**

There is not enough evidence regarding the safety and effectiveness of semi-invasive electrical bone growth stimulation (EBGS) as a treatment for any condition. In addition, no research-based clinical practice guidelines address semi-invasive EBGS. Therefore, semi-invasive EBGS is considered investigational for all indications.

**DEVICE REPLACEMENT OR REVISION**

In certain situations, an osteogenic stimulator may no longer be able to perform its basic function due to damage or wear. When a stimulator is out of its warranty period and cannot be repaired adequately to meet the patient's medical needs, replacement or revision of the device may be medically appropriate. Therefore, replacement or revision of all or part of a osteogenic stimulator may be considered medically necessary when device replacement Criteria are met.

In certain situations, an osteogenic stimulator may need to be revised to perform its basic function. Therefore, revision to an existing osteogenic stimulator may be considered medically necessary after the device has been placed.

When an osteogenic stimulator is in its warranty period or can be repaired or adapted adequately to meet the patient's medical needs, replacement of the device is not medically appropriate. Therefore, replacement of all or part of an osteogenic stimulator is considered not medically necessary when Criteria are not met.

## REFERENCES


1. Einhorn TA. Enhancement of fracture-healing. *The Journal of bone and joint surgery American volume.* 1995;77(6):940-56. PMID: 7782368
2. Buza JA, 3rd, Einhorn T. Bone healing in 2016. *Clin Cases Miner Bone Metab.* 2016;13:101-05. PMID: 27920804

3. Emami A, Petren-Mallmin M, Larsson S. No effect of low-intensity ultrasound on healing time of intramedullary fixed tibial fractures. *Journal of orthopaedic trauma.* 1999;13(4):252-7. PMID: 10342350
4. TEC Assessment 1992. "Electrical Bone Growth Stimulation for Delayed Union or Nonunion of Fractures." BlueCross BlueShield Association Technology Evaluation Center, Vol. 7, Tab 3.
5. Zura R, Xu ZJ, Della Rocca GJ, et al. When Is a Fracture Not "Fresh"? Aligning Reimbursement With Patient Outcome After Treatment With Low-Intensity Pulsed Ultrasound. *Journal of orthopaedic trauma.* 2017;31(5):248-51. PMID: 28134628
6. The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion Fractures 2005.
7. Bhandari M, Guyatt GH, Swiontkowski MF, et al. A lack of consensus in the assessment of fracture healing among orthopaedic surgeons. *Journal of orthopaedic trauma.* 2002;16(8):562-6. PMID: 12352564
8. Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J.* 2008;8(3):436-42. PMID: 17983841
9. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Cervical-Stim Model 505L Cervical Fusion System. 2004 [cited 08/15/2023]. 'Available from:' http://www.accessdata.fda.gov/cdrh_docs/pdf3/P030034b.pdf.
10. Aleem IS, Aleem I, Evaniew N, et al. Efficacy of Electrical Stimulators for Bone Healing: A Meta-Analysis of Randomized Sham-Controlled Trials. *Scientific reports.* 2016;6:31724. PMID: 27539550
11. Adie S, Harris IA, Naylor JM, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. *The Journal of bone and joint surgery American volume.* 2011;93(17):1569-76. PMID: 21915570
12. North American Spine Society (NASS) Coverage Policy Recommendations: Electrical Stimulation for Bone Healing. [cited 08/15/2023]. 'Available from:' https://www.spine.org/coverage.
13. Hannemann PF, Essers BA, Schots JP, et al. Functional outcome and cost-effectiveness of pulsed electromagnetic fields in the treatment of acute scaphoid fractures: a cost-utility analysis. *BMC Musculoskelet Disord.* 2015;16:84. PMID: 25880388
14. Beck BR, Matheson GO, Bergman G, et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. *Am J Sports Med.* 2008;36:545-53. PMID: 18055921
15. Saxena A, DiDomenico LA, Widtfeldt A, et al. Implantable electrical bone stimulation for arthrodeses of the foot and ankle in high-risk patients: a multicenter study. *J Foot Ankle Surg.* 2005;44(6):450-4. PMID: 16257674
16. Lau JT, Stamatis ED, Myerson MS, et al. Implantable direct-current bone stimulators in high-risk and revision foot and ankle surgery: a retrospective analysis with outcome assessment. *Am J Orthop (Belle Mead NJ).* 2007;36(7):354-7. PMID: 17694182
17. Resnick DK, Choudhri TF, Dailey AT, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg Spine.* 2005;2(6):737-40. PMID: 16028745
18. Kaiser MG, Eck JC, Groff MW, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators as an adjunct for lumbar fusion. *J Neurosurg Spine.* 2014;21(1):133-9. PMID: 24980594

## CODES

| Codes | Number | Description |
|---|---|---|
| CPT | None | |
| HCPCS | E0747 | Osteogenesis stimulator, electrical, noninvasive, other than spinal applications |
| | E0748 | Osteogenesis stimulator, electrical, noninvasive, spinal applications |
| | E0749 | Osteogenesis stimulator, electrical, surgically implanted |

***Date of Origin:*** *January 1996*