

Electrical Bone Growth Stimulators (Osteogenic Stimulation)

Effective: September 1, 2019

Next Review: August 2020

Last Review: August 2019

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. *Invasive* electrical bone growth stimulation may be considered **medically necessary** as an adjunct to spinal fusion surgery when clinical records document at least one 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. Current smoking habit (Note: Other tobacco use such as chewing tobacco is not considered a risk factor); or

- F. Diabetes; or
- G. Renal disease; or
- H. Alcoholism; or
- I. Significant osteoporosis which has been demonstrated on radiographs; or
- J. Systemic steroid use (e.g. daily dose ≥ 5 mg prednisone or equivalent for \geq three months) associated with low bone mass or bone loss.

II. *Noninvasive* electrical bone growth stimulation may be considered **medically necessary** when one of the following (A. or B.) is met:

- A. As an adjunct to spinal fusion surgery when clinical records document at least one of the risk factors in Criterion I.A-J.
- B. Treatment for any of the following conditions:
 - 1. 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
 - 2. Congenital pseudoarthroses; or
 - 3. Fracture nonunions meeting all of the following criteria:
 - a. Location in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities); and
 - b. At least 3 months have passed since the date of fracture; and
 - c. 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
 - d. The fracture gap is 1 cm or less; and
 - e. The patient can be adequately immobilized; and
 - f. The patient is of an age where he/she is likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

III. Invasive or noninvasive electrical bone growth stimulation device revision(s) or replacement(s) may be considered **medically necessary** after the device has been placed.

IV. Invasive or noninvasive electrical bone growth stimulation is considered **investigational** for the treatment of all other conditions, including but not limited to the following:

- A. Spinal fusion performed in the absence of any other risk factor(s) for failed spinal fusion (see criterion I.A-J for risk factors).
- B. Fresh fractures (defined as receiving treatment within one week of injury or open reduction) and stress fractures (defined as a fatigue-induced fracture resulting from repeated stress over time).

- C. Delayed union, defined as a decelerating fracture healing process as identified by serial x-rays.
- D. Acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis.
- E. Failed (non-spinal) joint fusion following arthrodesis 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.
- F. Osteonecrosis, defined as reduced blood flow to the bones in the joints.
- V. 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.

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
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. Non-Unions: Non-Union 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, and non-weight bearing status for lower extremity
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

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).

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

In 2008, Foley et al. published results of the industry-sponsored investigational device exemption (IDE) study of pulsed electromagnetic field (PEMF) stimulation as an adjunct to anterior cervical discectomy and fusion (ACDF) with anterior cervical plates and allograft interbody implants.^[1,2] 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 1 week after surgery, patients in the treatment group wore the Cervical-Stim device for 4 hours per day for 3 months.

Efficacy was measured by radiographic analysis at 1, 2, 3, 6, and 12 months. At 6 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, 7 in the PEMF group and 1 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 2 weeks of the 6-month postoperative window. Fusion rates for the 240 (74%) evaluable patients at 6 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 6 months, nonsignificant difference in fusion rates at 12 months, and lack of difference in functional outcomes at either 6 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 2 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

Delayed Union

Systematic Review

The 1992 BCBSA Technology (TEC) assessment^[3] did not find sufficient evidence to support the use of noninvasive EBGs for the treatment of delayed union in long or short bones.

The assessment of EBGs for the treatment of delayed union in long bones was based on one published randomized controlled trial. The assessment concluded that “the health outcomes data in this study do not show that noninvasive EBGs delivers an advantage over placebo.”^[3] In addition, the assessment identified two significant limitations of this trial:

- The long-term follow-up data on functional healing and need for subsequent surgery were not reported.
- Radiographic (intermediate outcome) evidence was difficult to interpret due to inconsistent rating methods and uncertain comparability in their findings.

The assessment identified no randomized trials of noninvasive EBGs for the treatment of delayed union in short bones. Instead, the assessment is based on three small case series and it concludes that the “evidence does not permit conclusions about whether health outcomes are improved” as a result of EBGs therapy.

Randomized Controlled Trials (RCTs)

Shi et al. reported a randomized sham-controlled trial that included 58 patients with delayed union of surgically-reduced long-bone fractures of the femur, tibia, humerus, radius, or ulna.^[4]

Delayed union was defined as a failure to heal after at least 16 weeks and not more than 9 months following surgical reduction and fixation of the fracture. Patients with fracture nonunion, defined as failure to heal after more than 9 months, were excluded from the study. Treatment with 8 hours of pulsed electromagnetic fields (PEMF) per day was stopped when no radiographic progression was observed over 3 months or when union was achieved, with union defined as no pain during joint stressing or during motion at the fracture site and callus bridging for 3 out of 4 cortices on blinded assessment. Three months of treatment resulted in a slight, but not statistically significant, improvement in the rate of union between PEMF-treated patients and controls (38.7% vs. 22.2%). The success rate was significantly greater with PEMF (77.4% vs. 48.1%) after an average of 4.8 months of treatment. The time to union was not significantly different between PEMF (4.8 months, range, 2 to 12) and sham controls (4.4 months, range 2 to 7).

Nonrandomized Studies

There are no new published observational studies on the use of noninvasive EBGs for the treatment of delayed unions.

Fresh/Acute Fractures

Randomized Controlled Trials (RCTs)

One sham-controlled RCT evaluated the impact of pulsed electromagnetic stimulation for acute tibial shaft fractures on the rate of surgical revision due to delayed union or non-union.^[5] At a 12-month follow-up, no significant between-group differences were found on surgical intervention for any reason.

Another, small (n=53), multicenter, double-blind, randomized sham-controlled trial found no advantage of PEMF for the conservative treatment of fresh (<5 days from injury) scaphoid fractures.^[6] Outcomes were assessed at 4, 6, 9, 12, 24 and 52 weeks and included the time to clinical and radiologic union and functional outcome. A 2014 update to this study which included 102 patients supported these findings.^[7]

Stress Fractures

Randomized Controlled Trial (RCT)

In 2008, Beck et al. reported a well-conducted randomized controlled trial (n=44) of capacitively coupled electric field stimulation for healing acute tibial stress fractures.^[8] 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.^[3] 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.^[9,10] 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.

AMERICAN ASSOCIATION OF NEUROLOGICAL SURGEONS (AANS) AND THE CONGRESS OF NEUROLOGICAL SURGEONS (CNS)^[11,12]

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.^[12] 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 [capacitively 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, including revision(s) and replacement(s) after the device has been placed, may be considered medically necessary as an adjunct to spinal fusion surgery when policy criteria are met.

Due to a lack of research, the use of noninvasive electrical bone growth stimulation as an adjunct to spinal fusion is considered investigational when spinal fusion is performed in the absence of any risk factor(s) for failed spinal fusion and when policy criteria are not met.

Spine Indications

There is enough research to show that noninvasive electrical bone growth stimulation results in a significantly higher spinal fusion rate. Therefore, noninvasive electrical bone growth stimulators, including revision(s) and replacement(s) after the device has been placed, are considered medically necessary for failed spinal fusion when policy criteria are met. Due to a lack of research, noninvasive electrical bone growth stimulators are considered investigational for spinal fusion performed in the absence of any other risk factor(s) and for failed spinal fusion when criteria are not met.

Non-Spine Indications

There is enough research to show that noninvasive electrical stimulators improve fracture healing for 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, including revision(s) and replacement(s) after the device has been placed, are considered medically necessary for fracture nonunion when policy criteria are met. In addition, noninvasive electrical bone growth stimulators, including revision(s) and replacement(s) after the device has been placed, are considered medically necessary for congenital pseudoarthroses.

However, there is not enough research to show that noninvasive electrical bone growth stimulators improve health outcomes for fracture nonunion in certain situations, and therefore are considered investigational when criteria are not met.

In addition, due to a lack of research, noninvasive electrical bone growth stimulation (EBGS) is considered investigational for the treatment of all other conditions including but not limited to, fresh fracture(s), delayed union, stress fracture(s), acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis, and failed joint fusion following arthrodesis.

INVASIVE ELECTRICAL BONE GROWTH STIMULATION (EBGS)

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 current clinical practice guidelines that recommend the use of invasive EBGS for patients with risk factors for failed fusion. Therefore, invasive EBGS, including revision(s) and replacement(s) after the device has been placed, may be considered medically necessary as an adjunct to spinal fusion surgery when policy criteria are met.

Due to a lack of research, the use of invasive electrical bone growth stimulation as an adjunct to spinal fusion is considered investigational when spinal fusion performed in the absence of any risk factor(s) for failed spinal fusion and when policy criteria are not met.

Spine and Non-Spine Indications

Due to a lack of research, invasive electrical bone growth stimulation (EBGS) is considered investigational for the treatment of all other conditions including but not limited to, spinal fusion performed in the absence of any other risk factor(s), fresh fracture(s), delayed union, stress fracture(s), acute or chronic spondylolysis (pars interarticularis defect) with or without spondylolisthesis, and failed joint fusion following arthrodesis.

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.

REFERENCES

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14. BlueCross BlueShield Association Medical Policy Reference Manual "Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures." Policy No. 7.01.85

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