Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 3/1/25**
(See policy history boxes for previous effective dates)

Title: Bone Growth Stimulation: Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Description/Background

ELECTRICAL BONE GROWTH STIMULATORS

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the chances of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion.

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

Invasive Stimulators

Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, with an accompanying electrode 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 Stimulators

Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using either 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 into a back brace or directly onto the skin and are worn for 6–8 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 Stimulators
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

The following implantable devices have received U.S. Food and Drug Administration (FDA) premarket approval (PMA):

- In 1986, the OsteoStim® (Electro-Biology, Inc.), which may also be marketed under the trade name SPF (Biomet), has received FDA PMA.

Noninvasive bone growth stimulators that have received FDA PMA include:

- The SpinalPak® bone growth stimulator system from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a capacitive coupling system, received PMA in 1999 for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.
- The EBI Bone Healing System® from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a pulsed electromagnetic field system which was first approved in 1979 with FDA PMA and indicated for nonunions, failed fusions, and congenitalpseudarthrosis. The device is secured with a belt around the waist.
- SpinaLogic Bone Growth Stimulator® (Regentek, a division of Orthopedics, LLC (formerly OrthoLogic, Tempe, AZ) received PMA in 1994 as a combined magnetic field portable device. This device is secured with a belt around the waist.
- Spinal-Stim Lite ® (Orthofix, Inc., Richardson, TX) received PMA in 1996 as a spinal adjunct to the Physio-Stim®. This device was approved to increase the probability of fusion success and as a non-operative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.
- The Cervical-Stim® from Orthofix, Inc., Richardson, TX is a pulsed electromagnetic field system that was approved in 2004 as an adjunct to cervical fusion surgery in patients at high risk for non-fusion. An illustration of how this particular device is worn is available at online site;
- In 2020, the ActaStim-S Spine Fusion Stimulator (Theragen, Inc.), was approved as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. This device is secured with a belt around the waist.

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

FDA product codes: LOE (invasive bone growth stimulator), LOF (noninvasive bone growth stimulator).

Medical Policy Statement

Invasive and noninvasive methods of electrical bone growth stimulation of the spine are **established.** They are useful therapeutic options when criteria are met.

Inclusionary and Exclusionary Guidelines

Inclusions:

- Invasive or noninvasive methods of electrical bone growth stimulation may be used as an *adjunct* to lumbar or cervical spinal fusion surgery in patients at high risk for fusion failure, defined as any **one** of the following criteria:
  - One or more previous failed spinal fusion(s)
  - Grade III or worse spondylolisthesis
  - Fusion to be performed at more than one level
  - Current tobacco use
  - Diabetes
  - Renal disease
  - Alcoholism
  - Immunocompromise
  - Systemic vascular disease
  - History of long term use of corticosteroids
  - Metabolic bone disease (including osteoporosis, osteopenia, and bone disease secondary to renal disease, nutritional deficiency, or conditions in which bone healing is likely to be compromised
- Noninvasive electrical bone stimulation may be considered medically necessary as a treatment of patients with failed lumbar or cervical spinal fusion. Failed spinal fusion is defined as a spinal fusion that 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.

Exclusions:

- Semi-invasive electrical stimulation.

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

20974 20975 E0748 E0749

Other codes (investigational, not medically necessary, etc.):

N/A

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Invasive Electrical Bone Growth Stimulation in Individuals at High-Risk of Lumbar Spinal Fusion Surgery Failure

Clinical Context and Therapy Purpose

The purpose of invasive electrical bone growth stimulation in individuals at high risk of lumbar spinal fusion surgery failure is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following **PICO** was used to select literature to inform this review.

Populations

The relevant population of interest are individuals at high risk of lumbar spinal fusion surgery failure.

Interventions

The therapy being considered is invasive electrical bone growth stimulation.

Comparators

The following practice is currently being used to treat individuals at high risk of lumbar spinal fusion surgery failure: lumbar spinal fusion surgery without invasive electrical bone growth stimulation.

Outcomes

The general outcomes of interest are symptoms, change in disease status, and functional outcomes.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

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

Review of Evidence

Instrumented Spinal Fusion
Kucharzyk (1999) reported on a controlled prospective nonrandomized trial of implantable electrical stimulation in patients undergoing instrumented posterior spinal fusion with pedicle screws.[1] A series of 65 patients who did not use electrical stimulation were compared with a later series of similar patients who did receive implantable electrical stimulation. Fusion success was 95.6% in the stimulated group compared to 87% in the nonstimulated group, a statistically significant difference. It appears that all patients had at least 1 or more high-risk factors for failed fusion, i.e., smoking history, prior surgery, multiple fusion levels, diabetes, etc. While this trial supports the use of electrical stimulation as an adjunct to instrumented posterior lumber fusion, it did not specifically identify the outcomes in patients considered to be at low risk for failed fusion.

Rogozinski and Rogozinski (1996) reported on the outcomes of 2 consecutive series of patients undergoing posterolateral fusions with autologous bone graft and pedicle screw fixation.[2] The first series of 41 patients were treated without electrical stimulation, while the second group of 53 patients received invasive electrical stimulation. Those receiving electrical stimulation reported a 96% fusion rate, compared to an 85% fusion rate in the unstimulated group. The fusion rate for patients receiving stimulation versus no stimulation was also significantly higher among those considered at high risk due to previous back surgery or multiple fusion levels. No significant increase in the fusion rate was noted among non-smokers (i.e., without a risk factor), but the comparative fusion rates for all patients without high-risk factors is not presented.

Non-instrumented Spinal Fusion
In 2009, Andersen et al published 2-year radiographic and functional outcomes from a European multicenter randomized controlled trial (RCT) of direct current (DC) stimulation with the SpF-XL IIb for posterolateral lumbar spinal fusion (PLF) in 98 patients older than age 60 years.[3] This age group has decreased fusion potential. In addition, instrumentation was not used due to risks related to longer operating times and screw loosening due to osteoporosis. All patients received fresh frozen allograft bone mixed with autograft obtained from the decompression procedure and were braced for 3 months after surgery. Dummy electrodes were placed in the control group to allow blinded radiographic evaluation, but patients and surgeons were not blinded to treatment group. Stimulator-specific complications included 3 cases of hematoma after removal of the battery and 2 patients who had pain at the site of the subcutaneous pocket. Three patients dropped out before the 1-year radiologic evaluation, 1

patient died, and an additional 25 patients did not complete the functional outcome questionnaires, resulting in 70% follow-up at 2-years. The percentage of dropouts was similar for the 2 treatments; patients who missed their 2-year evaluation had poorer outcomes on the Dallas Pain Questionnaire at the 1-year follow-up. Blinded evaluation of fusion by computed tomography (CT) scan indicated the same low percentage of cases with fusion in the 2 groups (33%). Fusion rates by plain radiographs were 57% in the control group (24/42) and 64% in the standard DC-stimulation group (27/42). Patients who achieved a solid fusion had better functional outcome and pain scores at their latest follow-up. At 2-year follow-up, electrical stimulation was associated with improved functional outcomes on 3 of 4 Dallas Pain Questionnaire subscales (daily activity, work/leisure, and social interest) but not for the Low Back Pain Rating Scale or the validated Short Form (SF)-36. These functional results have a high potential for bias due to the dropout of patients who had poorer outcomes and unequal patient expectation in this unblinded study.

In a 2010 publication, Anderson et al evaluated bone quality of the fusion mass in 80 of the patients described above (82% of 98) who underwent dual energy x-ray absorptiometry (DEXA) scanning to evaluate bone mineral density (BMD) at the 1-year follow-up.[4] This report describes 40 (n=46) and 100 (n=8) microAmp DC stimulation compared with a non-stimulated control condition (n=36). Fusion rates determined by CT scanning at the 2-year follow-up were 34% in the control group and 33% and 43% in the 40 and 100 microAmp groups, respectively (not significantly different). Patients classified as fused after 2 years had significantly higher fusion mass BMD at 1 year (0.592 vs. 0.466 g/cm^2), but DC electrical stimulation did not improve fusion mass bone quality (0.483 g/cm^2 for 40 microAmp; 0.458 g/cm^2 for 100 microAmp; 0.512 g/cm^2 for controls). Using linear regression, fusion mass bone quality was significantly influenced by gender, age of the patient, bone density of the remaining part of the lumbar spine, amount of bone graft applied, and smoking status.

Section Summary: Invasive Electrical Bone Growth Stimulation for Lumbar Spinal Fusion

Two RCTs have evaluated implantable electrical stimulation for bone growth stimulation, one in instrumented spinal fusion and one in noninstrumented spinal fusion, in patient populations at risk for failed fusion surgery. Although the studies had some risk for bias due to differential dropout rates, both showed improved fusion with electrical stimulation on blinded intermediate measures of radiographic fusion. These findings support the conclusion of improved functional outcomes with electrical stimulation.

Non-invasive Electrical Bone Growth Stimulation in Individuals at High-Risk of Lumbar Spinal Fusion Surgery Failure

Review of Evidence

Goodwin et al (1999) reported on the results of a study that randomly assigned 179 patients undergoing lumbar spinal fusions to receive or not receive capacitively coupled electrical stimulation.[5] A variety of surgical procedures both with and without instrumentation were used, and subjects were not limited to high-risk patients. The overall successful fusion rate was 84.7% for those in the active group compared to 64.9% in the placebo group, a statistically significant difference. While the actively treated group reported increased fusion success for all stratification groups (i.e., according to fusion procedure, single or multilevel fusion, smoking or nonsmoking group), in many instances, the differences did not reach statistical significance because of small numbers. For example, the subgroups in which there was not a significant

difference in fusion between the active and placebo groups included patients who had undergone previous surgery, smokers, and those with multilevel fusion. In addition, there were numerous dropouts in the study and a 10% noncompliance rate with wearing the external device for up to 9 months.

Mooney (1990) reported on the results of a double-blind study that randomly assigned 195 patients undergoing initial attempts at interbody lumber fusions with or without fixation to receive or not receive pulsed electromagnetic field electrical stimulation.[6] Patients were not limited to high-risk groups. In the active treatment group, the success rate was 92%, compared to 65% in the placebo group. On subgroup analysis, the treated group consistently reported an increased success rate. Subgroups included graft type, presence or absence of internal fixation, or presence or absence of smoking.

Linovitz et al (2002) conducted a double-blind clinical trial that randomly assigned 201 patients undergoing 1- or 2-level posterolateral fusion without instrumentation to undergo active or placebo electrical stimulation using a combined magnetic field device.[7] Unlike capacitively coupled or pulsed electromagnetic field devices, the combined magnetic field device requires a single 30-minute treatment per day with the device centered over the fusion site. Patients were treated for 9 months. Among all patients, 64% of those in the active group showed fusion at 9 months compared to 43% of those with placebo devices, a statistically significant difference. On subgroup analysis, there was a significant difference among women, but not men.

The two separate studies by Mooney and Linovitz both excluded patients with severe osteoporosis, and in the study by Goodwin et al excluded patients with osteoporosis of unspecified severity.[6,5,7] None of the studies mentioned steroid use; however, authors of two articles summarizing the available evidence on inhibition of bone healing[8] and the effects of drugs on bone healing[9] agree that long-term (longer than 1 week) steroid use has an inhibitory effect on bone healing. Thus, steroid use is added as an additional condition that results in high risk of non-fusion.

Subsection Summary: High Risk of Lumbar Spine Fusion Surgery Failure
Three RCTs identified assessed noninvasive electrical bone growth stimulation for spinal fusion surgery in patients at risk of fusion failure. Across the studies, treatment success rates were higher in groups receiving electrical stimulation.

Noninvasive Electrical Bone Growth Stimulation in Individuals with Failed Lumbar Spine Fusion Surgery

Review of Evidence
As noted, a TEC Assessment (1993) evaluated noninvasive electrical bone stimulation as a treatment of failed spinal fusion surgery (i.e., salvage therapy).[10] The TEC Assessment concluded that data from uncontrolled studies of patients with failed spinal fusion surgery suggested that noninvasive electrical stimulation results in a significantly higher fusion rate. The lack of controlled clinical trials was balanced by the fact that these patients served as their own controls.

Subsection Summary: Failed Lumbar Spine Fusion Surgery
The evidence is sufficient to show that noninvasive electrical stimulation improves fusion rates in this population.

Invasive or Noninvasive Electrical Bone Growth Stimulation in Cervical Spine Fusion Surgery

Review of Evidence

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.[11] This study described results using the Cervical-Stim device from Orthofix that received premarket approval (PMA) from the FDA in 2004.[12] A total of 323 patients were randomized, 163 to PEMF and 160 to no stimulation. All patients were active smokers (more than 1 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 non-evaluable 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 non-fusion.) 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 article.

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, non-significant 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.

Uncontrolled Studies

Coric et al (2018) published results from an industry-sponsored multicenter cohort study of pulsed electromagnetic field treatment in patients at high-risk of cervical arthrodesis following anterior cervical discectomy and fusion procedures.[13] The trial described results using the Cervical-Stim device (Orthofix) for 274 patients enrolled across 3 institutions. All patients had 1 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 pulsed electromagnetic field stimulation for 3 to 6 months. A historical control group was generated from a post hoc analysis of high-risk subjects from the original U.S. Food and Drug Administration (FDA) investigational device exemption trial. The primary endpoint was bone fusion rates as assessed at 6 and 12 months by the treating surgeon not blinded to clinical symptoms and outcomes for subjects. At 6 months, statistically significant improvements in fusion rates were found for patients falling into the following risk factor groups with i.e., at least 1 risk factor for: 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 with; i.e., at least 1 risk factor for: 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.

Section Summary: Invasive or Noninvasive Electrical Bone Growth Stimulation in Cervical Spinal Fusion Surgery

One RCT evaluating electrical bone growth stimulation was identified. Due to methodologic limitations in the only controlled trial published to date, the efficacy of electrical stimulation has not yet been established. An open-label multicenter cohort study provided evidence to demonstrate that patients at high-risk for arthrodesis following anterior cervical discectomy and fusion procedures reported statistically significant improvements in fusion rates with pulsed electromagnetic field stimulation. However, limitations in the study design, including use of a historical control group, lack of blinding, and no restrictions on surgical methods used by surgeons, preclude definitive assessments of the efficacy of pulsed electromagnetic field treatment in this high-risk population. Randomized controlled trials are required to establish the effectiveness of pulsed electromagnetic field treatment to improve cervical fusion rates.

SUMMARY OF EVIDENCE

For individuals who are at high risk of lumbar spinal fusion failure surgery who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews, a TEC Assessment, and randomized controlled trials. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials indicate that in patients with risk factors for failed fusion, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have failed lumbar spinal fusion surgery who receive noninvasive electrical bone growth stimulation, the evidence includes a TEC Assessment and studies with patients serving as their own controls. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Several RCTs have shown increased fusion rates with noninvasive bone stimulation in patient populations that include both high risk and normal risk groups. No studies were identified that studied a population of patients who were all at normal risk for fusion failure. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individual who are undergoing cervical spinal fusion surgery or have failed cervical spinal fusion who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes one randomized controlled trial. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is sufficient to determine the effects of the technology on health outcomes.

Ongoing and Unpublished Clinical Trials

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

SUPPLEMENTAL INFORMATION

Clinical Input Received through Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input from two physician specialty societies and three academic medical centers while this policy was under review for January 2011. Clinical input agreed with the criteria for high risk of fusion failure of the lumbar spine. The input on electrical stimulation for the cervical spine was mixed; specifically, some of those providing input agreed that data do not demonstrate improved outcomes with use of electrical stimulation in cervical spine fusion surgery. A majority of reviewers agreed that the large number of dropouts, non-significant difference in fusion rates by intent-to-treat analysis, and lack of data on functional outcomes (e.g., pain, return to usual activity) limited interpretation of the published study results.

PRACTICE GUIDELINES AND POSITION STATEMENTS

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

North American Spine Society (NASS)

In 2016, the NASS issued a coverage recommendation for electrical bone growth stimulators.[14]

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 (i.e., 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 (e.g., 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 (e.g., rheumatoid arthritis) that has required long-term corticosteroid therapy
    iii. Immunocompromised (e.g., 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 Congress of Neurological Surgeons (CNS)

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 conflict with the previous recommendations regarding bone growth stimulation.[15]

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 capacitive 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 4-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."[16]

Government Regulations

National:

NCD 150.2 "Electrical Osteogenic Stimulators," last updated 04/27/2005.
Electrical Osteogenic Stimulators[17]
A. General
Electrical stimulation to augment bone repair can be attained either invasively or non-invasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the non-invasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

Nationally Covered Indications

1. Noninvasive Stimulator
   The noninvasive stimulator device is covered only for the following indications:
   - Nonunion of long bone fractures;
   - Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
   - Congenital pseudarthrosis;
   - Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).
   - Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
   - Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

2. Invasive (Implantable) Stimulator
   The invasive stimulator device is covered only for the following indications:
   - Nonunion of long bone fractures;
   - Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc.).

- Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
- Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Nationally Non-Covered Indications

- Nonunion fractures of the skull, vertebrae and those that are tumor-related are excluded from coverage.
- Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.
- Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain non-covered.[22]

Local:

CGS Administrators, LLC. LCD for Osteogenesis Stimulators (L33796), Revision Effective Date: 01/01/2024.[18]

Indications and Limitations of Coverage and/or Medical Necessity

For any item to be covered by Medicare, it must 1) be eligible for a defined Medicare benefit category, 2) be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member, and 3) meet all other applicable Medicare statutory and regulatory requirements.

The purpose of a Local Coverage Determination (LCD) is to provide information regarding “reasonable and necessary” criteria based on Social Security Act § 1862(a)(1)(A) provisions.

In addition to the “reasonable and necessary” criteria contained in this LCD there are other payment rules, which are discussed in the following documents, that must also be met prior to Medicare reimbursement:

- The LCD-related Standard Documentation Requirements Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- The LCD-related Policy Article, located at the bottom of this policy under the Related Local Coverage Documents section.
- Refer to the Supplier Manual for additional information on documentation requirements.
- Refer to the DME MAC web sites for additional bulletin articles and other publications related to this LCD.

For the items addressed in this LCD, the “reasonable and necessary” criteria, based on Social Security Act § 1862(a)(1)(A) provisions, are defined by the following coverage indications, limitations and/or medical necessity.

A non-spinal electrical osteogenesis stimulator (E0747) is covered only if any of the following criteria are met:

1. Nonunion of a long bone fracture (see Appendices section) defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, or
2. Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery, or
3. Congenital pseudarthrosis.

Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a treating practitioner stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

A non-spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met:

1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery (see Appendices section), or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.

A spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

An ultrasonic osteogenesis stimulator (E0760) is covered only if all of the following criteria are met:

1. Nonunion of a fracture documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a treating practitioner stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; and
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if any of the criteria above are not met.

Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as not medically necessary.

Ultrasound conductive coupling gel is covered and separately payable if an ultrasonic osteogenesis stimulator is covered.

An ultrasonic osteogenesis stimulator will be denied as not medically necessary if it is used with other noninvasive osteogenesis stimulators.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

- Bone Growth Stimulation: Electrical Bone Growth Stimulation of the Appendicular Skeleton
- Bone Growth Stimulation: Ultrasound Accelerated Fracture Healing Device

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through September 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/13	2/19/13	3/7/13	Joint policy established. Topic split out from combined policy on bone stimulation, which included electrical stimulation of the appendicular skeleton, electrical stimulation of the spine, and ultrasound stimulation. Diverge from BCBSA regarding coverage for stimulator for specified conditions of the *cervical* spine
9/1/14	6/20/14	6/23/14	Routine maintenance
11/1/15	8/24/15	9/16/15	Routine maintenance
11/1/16	8/16/16	8/16/16	Routine policy maintenance.
11/1/17	8/15/17	8/15/17	Routine policy maintenance. Updated rationale section, added reference #18. No change in policy status.
11/1/18	8/21/18	8/21/18	Updated rationale section, added reference #15. No change in policy status.
11/1/19	8/20/19		Routine policy maintenance, no change in policy status.
11/1/20	8/18/20		Routine policy maintenance, no change in policy status.
11/1/21	8/17/21		Routine policy maintenance, no change in policy status.
11/1/22	8/16/22		Routine policy maintenance, no change in policy status.
3/1/23	12/20/22		Expanded on high-risk fusion failure conditions. Routine policy maintenance, no change in policy status.
3/1/24	12/19/23		Routine policy maintenance, no change in policy status. Vendor managed: N/A (ds)
3/1/25	12/17/24		Routine policy maintenance (jf) MPS-Removal of “The safety and effectiveness of”

			Vendor managed: N/A Northwood manages code HMO|PPO E0747

Next Review Date: 4th Qtr. 2025

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN: N/A	Revised: N/A
BCBSM: N/A	Revised: N/A

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: BONE GROWTH STIMULATION: ELECTRICAL STIMULATION OF THE SPINE AS AN ADJUNCT TO SPINAL FUSION PROCEDURES

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Covered; criteria apply.
BCNA (Medicare Advantage)	Refer to Government Regulations portion of the policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.