7.01.85	Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures		
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Section:	7.0 Surgery	**Page:**	Page 1 of 13

Policy Statement

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered **medically necessary** as an *adjunct* to lumbar spinal fusion surgery in patients at high risk for fusion failure, when any **one** of the following criteria exist:

- Alcoholism
- Current tobacco use
- Diabetes
- Fusion to be performed at more than 1 level
- Grade 3 or worse spondylolisthesis
- One or more previous failed spinal fusion(s)
- Renal disease
- Steroid use

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as a treatment for patients with failed lumbar spinal fusion surgery when **both** of the following criteria are met:

- Fusion that has not healed at a minimum of 6 months after the original surgery
- Serial radiographs over a course of 3 months show no evidence of progression of healing

Semi-invasive electrical bone growth stimulation is considered **investigational** as an adjunct to lumbar spinal fusion surgery and for failed lumbar fusion.

Invasive, semi-invasive, and noninvasive electrical bone growth stimulation are considered **investigational** as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

Policy Guidelines

Coding

There are specific CPT codes that describe electrical bone growth stimulation:

- **20974**: Electrical stimulation to aid bone healing; noninvasive (nonoperative)
- **20975**: Electrical stimulation to aid bone healing; invasive (operative)

There are specific HCPCS codes that describe electrical bone growth stimulation:

- **E0748**: Osteogenesis stimulator, electrical, noninvasive, spinal applications
- **E0749**: Osteogenesis stimulator, electrical, surgically implanted

Description

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 probability of obtaining a solid spinal fusion. Noninvasive devices have also been investigated in patients who are at normal risk of failed fusion and to treat a failed fusion.

Related Policies

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

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Regulatory Status

The following implantable device was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process:

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

The following noninvasive bone growth stimulators have been approved by the FDA through the premarket approval process:

- In 1999, the SpinalPak® bone growth stimulator system (Biolectron, a subsidiary of Electro-Biology), a capacitive coupling system, was approved for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.
- In 1979, the EBI Bone Healing System® (Biolectron, a subsidiary of Electro-Biology), a pulsed electromagnetic field system, was approved for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.
- In 1994, the SpinaLogic Bone Growth Stimulator® (Regentek, a division of dj Orthopedics [formerly OrthoLogic]) was approved as a combined magnetic field portable device. This device is secured with a belt around the waist.
- In 1996, the Spinal-Stim Lite® (Orthofix) was approved as a spinal adjunct to the Physio-Stim®. The Spinal-Stim Lite® device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of nine months has elapsed since the last surgery.
- In 2004, the Stim® (Orthofix), a pulsed electromagnetic field system, was approved as an adjunct to cervical fusion surgery in patients at high-risk for nonfusion.

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

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

Rationale

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 probability 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 surgical, noninvasive, and semi-invasive 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 six to nine 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 are worn for 24 hours a day until healing occurs, or for 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 six to eight hours a day for three to six months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying field onto an additional static magnetic field. This device involves 30 minutes of treatment daily 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.

Literature Review
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 technology, two domains are examined: the relevance, and 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.

Overview of Multiple Stimulation Types
This review was initially informed by 2, Blue Cross Blue Shield Association Technology Evaluation Center (TEC) Assessments (1992,1993) that evaluated electrical bone stimulation as an adjunct to spinal fusion surgery[1] or as a treatment of failed spinal fusion surgery (i.e., salvage therapy).[2] The TEC Assessments offered the following conclusions:

- Data from an RCT of patients meeting the criteria for high-risk for development of failed fusion suggested that *invasive or noninvasive* electrical bone stimulation as an adjunct to

spinal fusion surgery is associated with a significantly higher rate of spinal fusion success in the treated group than the control group.[3,4]

- 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.

A systematic review by Park et al (2014) offered a different conclusion.[5] Six RCTs through October 2013 were included, which investigated the effect of electrical stimulation vs no electrical stimulation on fusion rates after lumbar spinal fusion for the treatment of degenerative disease. The following types of electrical stimulation were included in the studies: direct current (three studies), pulsed electromagnetic field (PEMF; three studies), and capacitive coupling (one study). Control groups consisted of no stimulation (two studies) or placebo (four studies). Meta-analysis was not performed due to marked heterogeneity across study populations, study characteristics, and trial designs. Regardless of the type of electrical stimulation used, the cumulative incidences of fusion varied widely across RCTs and ranged from 35% to 91% in the intervention groups and from 33% to 82% in the control groups. Follow-up ranged from 9 to 24 months.

Lumbar Spinal Fusion
Invasive Electrical Bone Growth Stimulation

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.[6] A series of 65 patients who did not receive electrical stimulation were compared with a later series of similar patients who did receive implantable electrical stimulation. The fusion success rate was 95.6% in the stimulated group and 87% in the nonstimulated group, a statistically significant difference. It appears that all patients had at least one or more high-risk factors for failed fusion, including smoking history, prior surgery, multiple fusion levels, and diabetes. While this trial supported the use of electrical stimulation as an adjunct to instrumented posterior lumbar 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.[7] The first series of 41 patients was treated without electrical bone growth stimulation, while the second group of 53 patients received invasive electrical stimulation. Those receiving electrical stimulation reported a 96% fusion rate, compared with an 85% fusion rate in the nonstimulated group. The fusion rate for patients receiving stimulation vs 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 nonsmokers (i.e., without a risk factor), but comparative fusion rates for all patients without high-risk factors were not presented.

Noninstrumented Spinal Fusion
Andersen et al (2009) published 2-year radiographic and functional outcomes from a European multicenter RCT of direct current (DC) stimulation with the SpF-XL IIb for posterolateral lumbar spinal fusion in 98 patients older than age 60 years.[8,9] This age group has decreased fusion potential. Also, 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 three 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 three cases of hematoma after removal of the battery and two patients with pain at the site of the subcutaneous pocket. Three patients dropped out before the 1-year radiologic evaluation, 1 patient died, and 25 other patients did not complete the functional

outcome questionnaires, resulting in 70% follow-up at 2 years. The percentage of dropouts was similar for both treatments; patients who missed their two-year evaluation had poorer outcomes on the Dallas Pain Questionnaire at the one-year follow-up. Blinded evaluation of fusion by computed tomography scan indicated the same low percentage of cases with fusion in both groups (33%). Fusion rates by plain radiographs were 57% (24/42) in the control group and 64% (27/42) in the standard DC-stimulation group. Patients who achieved solid fusion had a better functional outcome and lower pain scores at their last 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, social interest) but not for the Low Back Pain Rating Scale or the 36-Item Short-Form Health Survey. These functional results have a high potential for bias due to the dropout rate among patients with poorer outcomes and the unequal patient expectation in this unblinded study.

Andersen et al (2010) evaluated the bone quality of the fusion mass in 80 (82%) of 98 patients previously described who underwent dual-energy x-ray absorptiometry scanning to evaluate bone mineral density at the 1-year follow-up.[10] This report described 40 (n=36) and 100 (n=8) microampere (μA) DC-stimulation compared with a nonstimulated control condition (n=36). Fusion rates determined by computed tomography scanning at the 2-year follow-up were 34% in the control group and 34% and 43% in the 40 and 100 μA groups, respectively (p=*NS*). Patients classified as fused after 2 years had significantly higher fusion mass bone mineral density at 1 year (0.592 g/cm^2 vs 0.466 g/cm^2), but DC electrical stimulation did not improve fusion mass bone quality (0.483 g/cm^2 for 40 μA vs 0.458 g/cm^2 for 100 μA vs 0.512 g/cm^2 for controls). Using linear regression, fusion mass bone quality was significantly influenced by sex, patient age, 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.

Noninvasive Electrical Bone Growth Stimulation
High-Risk of Lumbar Spine Fusion Failure
Goodwin et al (1999) reported on the results of a study that randomized 179 patients undergoing lumbar spinal fusions to receive or not to receive capacitively coupled electrical stimulation.[11] A variety of surgical procedures, both with and without instrumentation were used, and patients were not limited to high-risk groups. The overall successful fusion rate was 84.7% for those in the active treatment group compared with 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 were not statistically significant because of small numbers. For example, among the subgroups in which there was no significant difference in fusion rates between the active and placebo groups, patients who had undergone previous surgery, smokers, and those with multilevel fusion were included. Also, there were numerous dropouts in the study and a 10% noncompliance rate among those wearing the external device for up to nine months.

Mooney (1990) reported on the results of a double-blind study that randomized 195 patients undergoing initial attempts at interbody lumbar fusions with or without fixation to receive or not to receive PEMF stimulation.[4] Patients were not limited to high-risk groups. In the active treatment group, the success rate was 92%, compared with 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 RCT that assigned 201 patients undergoing 1- or 2-level posterolateral fusion without instrumentation to active or placebo electrical stimulation using a combined magnetic field device.[12] Unlike capacitively coupled or PEMF devices, the combined magnetic field device requires a single, 30-minute treatment per day with the device centered on the fusion site. Patients were treated for nine months. Among all patients, 64% of those in the active group showed fusion at 9 months compared with 43% of those with placebo devices, a statistically significant difference. On subgroup analysis, there was a significant difference among women, but not men.

The studies by Mooney (1990) and Linovitz et al (2002) both excluded patients with severe osteoporosis, and in the study by Goodwin et al (1999), patients with osteoporosis of unspecified severity were excluded.[4,11,12] None of the studies mentioned steroid use; however, authors of two articles summarizing the available evidence on inhibition of bone healing[13] and the effects of drugs on bone healing[14] agreed that long-term (>1 week) steroid use has an inhibitory effect on bone healing. Thus, steroid use is added as another factor that results in a high-risk of nonfusion.

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.

Failed Lumbar Spine Fusion Surgery
As noted, a TEC Assessment (1993) evaluated noninvasive electrical bone stimulation as a treatment of failed spinal fusion surgery (i.e., salvage therapy).[2] 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.

Cervical Spine Fusion
Coric et al (2018) published results from an industry-sponsored multicenter cohort study of PEMF treatment in patients at high-risk of cervical arthrodesis following anterior cervical discectomy and fusion procedures.[15] 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 PEMF stimulation for 3 to 6 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 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; 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; 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.

Foley et al (2008) published results from the industry-sponsored investigational device exemption trial of PEMF stimulation as an adjunct to anterior cervical discectomy and fusion with anterior cervical plates and allograft interbody implants.[16] This trial described results using the Cervical-Stim device (Orthofix) that received premarket approval from the FDA in 2004.[17] A total of 323 patients were randomized, 163 to PEMF stimulation and 160 to no stimulation. All patients were active smokers (>1 pack of cigarettes per day, 164 patients) or were undergoing multilevel anterior cervical discectomy and fusion (192 patients). Patients with a pertinent history of trauma, previous posterior cervical approach or revision surgery, certain systemic conditions or steroid use, and regional conditions (e.g., Paget disease, spondylitis) were excluded. Beginning one week after surgery, patients in the treatment group wore the Cervical-Stim device for four hours a day for three 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 inevaluable radiographs or radiographs not taken 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=0.007). By intention-to-treat analysis, assuming that nonevaluable patients did not have fusion, PEMF, and control group fusion rates were 65.6% and 56.3%, respectively; these rates did not differ significantly (p=0.084). The FDA analysis, however, indicated that the results at six months still differed statistically 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 (92.8%) of 125 PEMF patients and 104 (86.7%) of 120 control patients; these rates did not differ significantly (p=0.113). Patient compliance, which was automatically monitored by the device, was assessed at each visit; however, compliance data were not reported 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 pain assessment on the visual analog scale, and no worsening in Neck Disability Index score, the study found no statistically significant differences between groups in the percentages 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 intention-to-treat 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 did not support the efficacy of this device.

A case report of electrical stimulation as an adjunct to cervical fusion, reported by Mackenzie and Veninga (2004), described treatment with PEMF stimulation for delayed union of anterior cervical fusion.[18]

Section Summary: Cervical Spine Fusion
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 PEMF 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 PEMF treatment in this high-risk population. RCTs are required to establish the effectiveness of PEMF treatment to improve cervical fusion rates.

Summary of Evidence
For individuals who are at high-risk of lumbar spinal fusion surgery failure who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews, a TEC

Assessment, and RCTs. The relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials have indicated that in patients with risk factors for failed fusion surgery, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine 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. The relevant outcomes are symptoms, change in disease status, and functional outcomes. Data have shown that noninvasive electrical stimulation improves fusion rates in this population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing cervical spinal fusion surgery or have failed cervical spine fusion who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes an RCT. The relevant outcomes are symptoms, change in disease status, and functional outcomes. The only controlled trial published to date had methodologic limitations, and the efficacy of electrical stimulation in the cervical spine has not 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 treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Supplemental Information

Clinical Input From 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 from Blue Cross Blue Shield Association, input was received from 2 physician specialty societies and 3 academic medical centers in 2011. Input agreed with the criteria for high-risk of fusion failure of the lumbar spine. Input on electrical stimulation for the cervical spine was mixed; specifically, some reviewers input agreed that data do not demonstrate improved outcomes with use of electrical stimulation in cervical spine fusion surgery. Most reviewers agreed that the large number of dropouts, nonsignificant difference in fusion rates by intention-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

North American Spine Society

The North American Spine Society (2016) issued a coverage recommendation for electrical bone growth stimulators, which stated the following[19]:

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 and Congress of Neurological Surgeons
Updated guidelines from the American Association of Neurological Surgeons and the Congress of Neurological Surgeons (2014) indicated that there was no evidence published after their 2005 guidelines that conflicts with the previous recommendations on bone growth stimulation.[20]

Based on a single-level II study (2009), the routine use of direct current stimulation in patients older than age 60 years was not recommended. Use of direct current stimulation 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, concerns about 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 as a treatment alternative to revision surgery in patients presenting with pseudoarthrosis following posterolateral lumbar fusion (single-level IV study). No additional studies investigating the efficacy of capacitively coupled electrical stimulation were identified.

The 2 medical associations also issued guidelines in 2005 that stated there was class II and III evidence (nonrandomized comparative trials and case series):

> "...to support the use of direct current stimulation or [capacitive 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."[21]

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage

Medicare covers noninvasive electrical stimulators for the following[22]:

- "Failed fusion, where a minimum of 9 months has elapsed since the last surgery" and
- "…as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis 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)."

Medicare covers invasive electrical stimulators:

- "…as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis 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)."

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in March 2018 did not identify any ongoing or unpublished trials that would likely influence this review.

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Documentation for Clinical Review

Please provide the following documentation (if/when requested):

- History and physical and/or consultation notes including:
  - Previous treatment plan and response
- Initial and serial radiologic reports for the past three months
- Progress notes for the past three months
- Previous operative reports

Post Service

- Results/reports of tests performed
- Procedure report(s)

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

MN/IE

The following services may be considered medically necessary in certain instances and investigational in others. Services may be considered medically necessary when policy criteria are met. Services may be considered investigational when the policy criteria are not met or when the code describes application of a product in the position statement that is investigational.

Type	Code	Description
CPT®	20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
	20975	Electrical stimulation to aid bone healing; invasive (operative)
HCPCS	E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
	E0749	Osteogenesis stimulator, electrical, surgically implanted
ICD-10 Procedure	00HU0MZ	Insertion of Neurostimulator Lead into Spinal Canal, Open Approach
	00HU3MZ	Insertion of Neurostimulator Lead into Spinal Canal, Percutaneous Approach
	00HU4MZ	Insertion of Neurostimulator Lead into Spinal Canal, Percutaneous Endoscopic Approach
	00HV0MZ	Insertion of Neurostimulator Lead into Spinal Cord, Open Approach
	00HV3MZ	Insertion of Neurostimulator Lead into Spinal Cord, Percutaneous Approach
	00HV4MZ	Insertion of Neurostimulator Lead into Spinal Cord, Percutaneous Endoscopic Approach
	00PV0MZ	Removal of Neurostimulator Lead from Spinal Cord, Open Approach
	00PV3MZ	Removal of Neurostimulator Lead from Spinal Cord, Percutaneous Approach
	00PV4MZ	Removal of Neurostimulator Lead from Spinal Cord, Percutaneous Endoscopic Approach
	00WU0MZ	Revision of Neurostimulator Lead in Spinal Canal, Open Approach
	00WU3MZ	Revision of Neurostimulator Lead in Spinal Canal, Percutaneous Approach
	00WU4MZ	Revision of Neurostimulator Lead in Spinal Canal, Percutaneous Endoscopic Approach
	00WV0MZ	Revision of Neurostimulator Lead in Spinal Cord, Open Approach
	00WV3MZ	Revision of Neurostimulator Lead in Spinal Cord, Percutaneous Approach
	00WV4MZ	Revision of Neurostimulator Lead in Spinal Cord, Percutaneous Endoscopic Approach

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
10/15/2007	New policy Separated non-invasive policy from invasive.	Medical Policy Committee
04/01/2011	Policy title change from Electrical Bone Growth Stimulation of the Appendicular Skeleton and Spine without position change	Medical Policy Committee
12/15/2014	Policy title change from Electrical Bone Growth Stimulation	Medical Policy Committee

Effective Date	Action	Reason
	Policy revision with position change effective 2/15/2015	
02/15/2015	Policy revision with position change	Medical Policy Committee
07/01/2016	Policy revision with position change	Medical Policy Committee
06/01/2017	Policy revision without position change	Medical Policy Committee
06/01/2018	Policy revision without position change	Medical Policy Committee
06/01/2019	Policy revision without position change	Medical Policy Committee

Definitions of Decision Determinations

Medically Necessary: A treatment, procedure, or drug is medically necessary only when it has been established as safe and effective for the particular symptoms or diagnosis, is not investigational or experimental, is not being provided primarily for the convenience of the patient or the provider, and is provided at the most appropriate level to treat the condition.

Investigational/Experimental: A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

Split Evaluation: Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department. Please call (800) 541-6652 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.