BlueCross BlueShield of Alabama

Name of Policy:

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Policy #: 524
Category: DME

Latest Review Date: May 2018
Policy Grade: B

Background/Definitions:

As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. *The technology must have final approval from the appropriate government regulatory bodies;*
2. *The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;*
3. *The technology must improve the net health outcome;*
4. *The technology must be as beneficial as any established alternatives;*
5. *The improvement must be attainable outside the investigational setting.*

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. *In accordance with generally accepted standards of medical practice; and*
2. *Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient's illness, injury or disease; and*
3. *Not primarily for the convenience of the patient, physician or other health care provider; and*
4. *Not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.*

Description of Procedure or Service:

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.

Invasive Stimulators

Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is 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 to 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.

Policy:

Non-invasive and invasive electrical bone growth stimulation (**E0748, E0749) meets** Blue Cross and Blue Shield of Alabama's medical criteria for coverage as an *adjunct* to **lumbar spinal fusion** surgery for patients at high risk of pseudarthrosis, including those with one or more of the following conditions:

- One or more previously failed spinal fusion (s) (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);
- Grade III or worse spondylolisthesis;
- Fusion to be performed at more than one level;
- Current smoking habit;
- Diabetes;
- End Stage Renal disease;

- Alcoholism; current or recent history of alcoholism;
- Osteoporosis (significant, as demonstrated by imaging studies);
- Steroid use.

Semi-invasive electrical stimulation does not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage as an adjunct to lumbar fusion surgery and for failed lumbar fusion and is considered **investigational.**

Invasive, semi-invasive, and noninvasive electrical stimulation do not meet Blue Cross and Blue Shield of Alabama's medical criteria for coverage as an adjunct to cervical fusion surgery and for failed cervical spine fusion and are considered **investigational.**

Blue Cross and Blue Shield of Alabama does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Cross and Blue Shield of Alabama administers benefits based on the member's contract and corporate medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

Key Points:

The most recent literature review was updated through February 14, 2018 with search of MEDLINE database.

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.

Overview of Multiple Stimulation Types

The evidence review regarding electrical bone stimulation as an adjunct to spinal fusion surgery or as a treatment of failed spinal fusion surgery (i.e., salvage therapy) was initially based on 2 TEC Assessments. The initial TEC Assessments offered the following conclusions:

- Data from a randomized, controlled clinical trial of patients meeting the criteria for high risk for development of failed fusion suggest that *invasive or noninvasive* electrical bone stimulation as an adjunct to spinal fusion surgery is associated with a significantly higher spinal fusion success rate in the treated group compared with the control group.
- Data from uncontrolled studies of patients with failed spinal fusion suggest that noninvasive electrical stimulation results in a significantly higher fusion rate. The lack of controlled clinical trials is balanced by the fact that these patients served as their own controls.

A 2014 systematic review by Park et al offered a different conclusion. Six RCTs through October 2013 were included, and investigated the effect of electrical stimulation versus 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 (3 studies), pulsed electromagnetic field (3 studies), and capacitive coupling (1 study). Control groups consisted of no stimulation (2 studies) or placebo (4 studies). A meta-analysis was not performed due to marked heterogeneity in the study populations, characteristics, and designs. Regardless of the type of electrical stimulation used, the cumulative incidences of fusion varied widely across RCTs and ranged from about 35% to 91% in the intervention groups and from about 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. 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. 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. 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. 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 one year radiologic evaluation, one 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 one 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 36-Item Short-Form Health Survey. 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 one year follow-up. 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 one year (0.592 vs. 0.466 g/cm2), but DC electrical stimulation did not improve fusion mass bone quality (0.483 g/cm2 for 40 microAmp; 0.458 g/cm2 for 100 microAmp; 0.512 g/cm2 for controls). Using linear regression, fusion mass bone quality was significantly influenced by sex, age of the patient, bone density of the remaining part of the lumbar spine, amount of bone graft applied, and smoking.

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 Stimulation

High Risk of Lumbar Spine Fusion Failure

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. 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. 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. 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 with 43% of those with placebo devices, a statistically significant difference. On subgroup analysis, there was a significant difference among women, but not men.

Mooney et al and Linovitz et al excluded from their studies patients with severe osteoporosis, and Goodwin et al excluded patients with osteoporosis of unspecified severity. None of the studies mentioned steroid use; however, authors of 2 articles summarizing the available evidence on inhibition of bone healing and the effects of drugs on bone healing agree that long-term (>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 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). 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
In 2008, Foley et al published results of the industry-sponsored investigational device exemption 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. This study described results using the Cervical-Stim device from Orthofix that received premarket approval from 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 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 disease or spondylitis were excluded. Beginning one week after surgery, patients in the treatment group wore the Cervical-Stim device for 4 hours per day for 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 one control violated study protocol, and 19 in the PEMF group and 28 controls had radiographs that were not evaluable or radiographs that were not done within 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 (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=0.084). (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=0.113). 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 FDA. With clinical success defined as no worsening in neurologic function, an improvement in visual analog scale 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.

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.

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. 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 investigational device exemption trial. The primary end point 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.

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 failure surgery who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews, a TEC Assessment, and randomized controlled trials (RCTs). 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, 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. 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. 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.

Practice Guidelines and Position Statements
North American Spine Society
In 2016, the North American Spine Society (NASS) issued a coverage recommendation for electrical bone growth stimulators.

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, hypogammaglobinemia, 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."

<u>American Association of Neurological Surgeons/Congress of Neurological Surgeons</u>
Updated 2014 guidelines from the American Association of Neurological Surgeons (AANS) and the Congress of Neurological Surgeons (CNS) have indicated that there was no evidence published after their 2005 guidelines that conflict with the previous recommendations on bone growth stimulation.

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, 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 (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 and CNS guidelines stated that 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."

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

Key Words:

Bone Growth Stimulation, Spine, Electrical Bone Growth Stimulation, Electrical Stimulation, Spinal Fusion, Cervical-Stim, EBI Bone Healing System, OsteoStim, SpinalPak, SpinaLogic Bone Growth Stimulator, Spinal-Stim Lite

Approved by Governing Bodies:

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

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

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

- In 1999, the SpinalPak® bone growth stimulator system (Biolectron, a subsidiary of Electro-Biology, Parsippany, NJ), a capacitive coupling system, was approved by FDA through the premarket approval process 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, Parsippany, NJ), a pulsed electromagnetic field system, approved by FDA through the premarket approval process 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, Tempe, AZ]) was approved by FDA through the premarket approval process as a combined magnetic field portable device. This device is secured with a belt around the waist.
- In 1996, the Spinal-Stim Lite ® (Orthofix, Richardson, TX) was approved by FDA through the premarket approval process as a spinal adjunct to the Physio-Stim®. This 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 9 months has elapsed since the last surgery.
- In 2004, the Stim® (Orthofix, Richardson, TX), a pulsed electromagnetic field system, was approved by FDA through the premarket approval process 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 FDA approval or clearance.

Benefit Application:

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.
ITS: Home Policy provisions apply.
FEP: Special benefit consideration may apply. Refer to member's benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.

Current Coding:

CPT Codes:

20974	Electrical stimulation to aid bone healing; non-invasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes:

E0748	Osteogenesis stimulator, electrical, noninvasive, spinal application
E0749	Osteogenesis stimulator, electrical (surgically implanted)

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Policy History:

Medical Policy Group, October 2008 **(4)**
Medical Policy Administration Committee, November 2008
Available for comment November 20, 2008-January 5, 2009
Medical Policy Group, February 2009 **(4)**
Medical Policy Administration Committee, March 2009
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Medical Policy Group, October 2009 **(1)**
Medical Policy Administration Committee, October 2009
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Medical Policy Administration Committee, December 2009
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Medical Policy Group, February 2010 **(1)**
Medical Policy Administration Committee, April 2010
Available for comment April 7-May 21, 2010
Medical Policy Group, February 2010; Regular update **(1)**
Medical Policy Group, November 2011 **(1):** Electrical bone growth stimulators separated from policy #331; Update to Key Points and References; no change in policy statement
Medical Policy Administration Committee, January 2012
Available for comment January 11 – February 27, 2012
Medical Policy Panel, October 2012
Medical Policy Group, March 2013 **(1):** Electrical Stimulation of the Spine separated from policy #082; Update to Approved by Governing Bodies; updated literature search; no change in policy statement
Medical Policy Panel, October 2013
Medical Policy Group, October 2013 **(1):** Updated literature search; no change to policy statement
Medical Policy Panel, October 2014
Medical Policy Group, October 2014 **(5):** Updated Practice Guidelines and Position Statements and added Reference to support; no change to policy statement
Medical Policy Panel April 2016
Medical Policy Group, April 2016 **(6)**: Updated Key Points and References; no change to policy statement.
Medical Policy Panel, May 2017
Medical Policy Group, May 2017 **(6)**: Updates to Key Points, Practice Guidelines and References. Added "lumbar" to policy statement for clarification.
Medical Policy Panel, April 2018
Medical Policy Group, May 2018 **(6)**: Updates to Key Points and References.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.