

Protocol

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

(70185)

Medical Benefit		Effective Date: 07/01/12	Next Review Date: 01/21
Preauthorization	Yes	Review Dates: 09/07, 09/08, 09/09, 05/10, 05/11, 05/12, 05/13, 05/14, 01/15, 01/16, 01/17, 01/18, 01/19, 01/20	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • Who are at high risk of lumbar spinal fusion failure surgery	Interventions of interest are: • Invasive electrical bone growth stimulation	Comparators of interest are: • Lumbar spinal fusion surgery without electrical bone growth stimulation	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • Who are at high risk of lumbar spinal fusion failure surgery	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • Lumbar spinal fusion surgery without electrical bone growth stimulation	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • With failed lumbar spinal fusion surgery	Interventions of interest are: • Noninvasive electrical bone growth stimulation	Comparators of interest are: • Surgery • Conservative management	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes
Individuals: • Who are undergoing cervical spinal fusion surgery or have failed cervical spine fusion	Interventions of interest are: • Invasive or noninvasive electrical bone growth stimulation	Comparators of interest are: • Cervical spinal fusion surgery without electrical bone growth stimulation • Conservative management	Relevant outcomes include: • Symptoms • Change in disease status • Functional outcomes

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.

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 randomized controlled trials. 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. 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 a randomized controlled trial. 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.

POLICY

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, defined as any one of the following criteria:

- one or more previous failed spinal fusion(s);
- grade 3 or worse spondylolisthesis;
- fusion to be performed at more than one level;
- current tobacco use;
- diabetes;
- renal disease;
- alcoholism; or
- steroid use.

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as a treatment for patients with failed lumbar spinal fusion surgery. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of six months after the original surgery, as evidenced by serial radiographs over a course of three months.

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.

MEDICARE ADVANTAGE

For Medicare Advantage invasive electrical stimulation of the spine is **medically necessary** 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 three or more vertebrae.

The noninvasive stimulator device is **medically necessary** for failed fusion, where a minimum of nine months has elapsed since the last surgery and 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 three or more vertebrae.

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 nine 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 nine 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 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 (Bioelectron, 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® (Bioelectron, 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).

RELATED PROTOCOLS

Electrical Bone Growth Stimulation of the Appendicular Skeleton

Ultrasound Accelerated Fracture Healing Device

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

1. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation as an adjunct to spinal fusion surgery (invasive method). TEC Evaluations. 1992;324-351.
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation in association with spinal fusion surgery (noninvasive method). TEC Evaluations. 1993:1-12.
3. Kane WJ. Direct current electrical bone growth stimulation for spinal fusion. *Spine (Phila Pa 1976)*. Mar 1988;13(3):363-365. PMID 3291140
4. Mooney V. A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions. *Spine (Phila Pa 1976)*. Jul 1990;15(7):708-712. PMID 2218718
5. Park P, Lau D, Brodt ED, et al. Electrical stimulation to enhance spinal fusion: a systematic review. *Evid Based Spine Care J*. Oct 2014;5(2):87-94. PMID 25278882
6. Kucharzyk DW. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. *Spine (Phila Pa 1976)*. Mar 1 1999;24(5):465-468; discussion 469. PMID 10084185
7. Rogozinski A, Rogozinski C. Efficacy of implanted bone growth stimulation in instrumented lumbosacral spinal fusion. *Spine (Phila Pa 1976)*. Nov 1 1996;21(21):2479-2483. PMID 8923635
8. Andersen T, Christensen FB, Egund N, et al. The effect of electrical stimulation on lumbar spinal fusion in older patients: a randomized, controlled, multi-center trial: part 2: fusion rates. *Spine (Phila Pa 1976)*. Oct 1 2009;34(21):2248-2253. PMID 19934803
9. Andersen T, Christensen FB, Ernst C, et al. The effect of electrical stimulation on lumbar spinal fusion in older patients: a randomized, controlled, multi-center trial: part 1: functional outcome. *Spine (Phila Pa 1976)*. Oct 1 2009;34(21):2241-2247. PMID 19934802
10. Andersen T, Christensen FB, Langdahl BL, et al. Fusion mass bone quality after uninstrumented spinal fusion in older patients. *Eur Spine J*. Dec 2010;19(12):2200-2208. PMID 20429017
11. Goodwin CB, Brighton CT, Guyer RD, et al. A double-blind study of capacitively coupled electrical stimulation as an adjunct to lumbar spinal fusions. *Spine (Phila Pa 1976)*. Jul 1 1999;24(13):1349-1356; discussion 1357. PMID 10404578
12. Linovitz RJ, Pathria M, Bernhardt M, et al. Combined magnetic fields accelerate and increase spine fusion: a double-blind, randomized, placebo controlled study. *Spine (Phila Pa 1976)*. Jul 1 2002;27(13):1383-1389; discussion 1389. PMID 12131732
13. Gaston MS, Simpson AH. Inhibition of fracture healing. *J Bone Joint Surg Br*. Dec 2007;89(12):1553-1560. PMID 18057352
14. Pountos I, Georgouli T, Blokhuis TJ, et al. Pharmacological agents and impairment of fracture healing: what is the evidence? *Injury*. Apr 2008;39(4):384-394. PMID 18316083
15. Coric D, Bullard DE, Patel VV, et al. Pulsed electromagnetic field stimulation may improve fusion rates in cervical arthrodesis in high-risk populations. *Bone Joint Res*. Feb 2018;7(2):124-130. PMID 29437635
16. Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine J*. May-Jun 2008;8(3):436-442. PMID 17983841
17. U.S. Food and Drug Administration. Summary of Safety and Effectiveness Data: Cervical-Stim Model 505L Cervical Fusion System. 2004; https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030034b.pdf. Accessed March 12, 2018.
18. Mackenzie D, Veninga FD. Reversal of delayed union of anterior cervical fusion treated with pulsed electromagnetic field stimulation: case report. *South Med J*. May 2004;97(5):519-524. PMID 15180031
19. North American Spine Society (NASS). NASS Coverage Policy Recommendations: Electrical Stimulation for Bone Healing. 2016; <https://www.spine.org/PolicyPractice/CoverageRecommendations/AboutCoverageRecommendations.aspx>. Accessed March 12, 2018.

20. Kaiser MG, Eck JC, Groff MW, et al. Guideline update for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators as an adjunct for lumbar fusion. *J Neurosurg Spine*. Jul 2014;21(1):133-139. PMID 24980594
21. Resnick DK, Choudhri TF, Dailey AT, et al. Guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg Spine*. Jun 2005;2(6):737-740. PMID 16028745
22. Centers for Medicare & Medicaid Services. National Coverage Determination for Osteogenic Stimulators (150.2). 2005; https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&DocID=150.2&ncd_id=150.2&ncd_version=2&basket=ncd%25253A150%25252E2%25253A2%25253AOsteogenic+Stimulators&bc=gAAAABAAAAAAAA%3d%3d&. Accessed March 12, 2018.