

MEDICAL POLICY – 7.01.85

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

BCBSA Ref. Policy: 7.01.85

Effective Date: July 1, 2024
Last Revised: June 10, 2024
Replaces: 7.01.571

RELATED MEDICAL POLICIES:

1.01.05	Low Intensity Pulsed Ultrasound Fracture Healing Device
7.01.07	Electrical Bone Growth Stimulation of the Appendicular Skeleton
7.01.542	Lumbar Spinal Fusion

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Introduction

Spinal fusion is a surgery that causes the bones of the spine (the vertebrae) to grow together and become like one bone. A graft is used, and then the body's own processes create the fusion over time. In some cases, the fusion processes can be helped along with electrical stimulation. Stimulators send electrical pulses or current through tissues, toward the bone. Electrical bone growth stimulators appear to make bone cells grow. Electrical bone growth stimulators are either noninvasive, invasive (implantable), or semi-invasive (semi-implantable).

- Noninvasive stimulators deliver current through small patches (electrodes) or coils placed on the skin.
- Invasive electrical stimulation use devices that are implanted in the body.
- Semi-invasive stimulators use needle-like electrodes placed through the skin.

This policy discusses when noninvasive and invasive electrical bone growth stimulators may be considered medically necessary for spinal fusions. Semi-invasive stimulators are considered investigational (unproven) for spinal fusions.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can

be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Stimulation	Medical Necessity
Invasive or noninvasive electrical bone growth stimulation	<p>Either invasive or noninvasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to lumbar spinal fusion surgery in individuals at high risk for fusion failure, defined as having ANY one of the following criteria:</p> <ul style="list-style-type: none">• Alcoholism• Current tobacco use• Diabetes• Fusion to be performed at more than one level• Grade III or worse spondylolisthesis• One or more previous failed spinal fusion(s)• Renal disease• Steroid use <p>Noninvasive electrical bone growth stimulation may be considered medically necessary as a treatment for individuals with failed lumbar spinal fusion surgery.*</p> <p>Note: *Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial radiographs over a course of 3 months.</p>



Stimulation	Investigational
Semi-invasive electrical bone growth stimulation	Semi-invasive electrical bone growth stimulation is considered investigational as an adjunct to lumbar fusion surgery and for failed lumbar fusion.
Invasive, semi-invasive, and noninvasive electrical bone growth stimulation	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.

Documentation Requirements

The individual's medical records submitted for review should document that medical necessity criteria are met. The record should include clinical documentation of:

- Diagnosis/condition
- History and physical examination documenting the severity of the condition
- Level(s) planned for fusion
- Risk factors that place member at high risk of fusion failure OR imaging that shows failure of fusion

Coding

Code	Description
CPT	
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
HCPCS	
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

Note: CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).



Related Information

Benefit Application

While invasive electrical stimulation will be billed as a component of the hospital charge, noninvasive devices may be adjudicated according to the member's benefits for durable medical equipment.

Evidence Review

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 individuals who are at normal risk of failed fusion and to treat a failed fusion.

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. 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 by 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 six to eight hours per day for three to six 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 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.

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 (RCTs). Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials have indicated that in individuals 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 an 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 individuals 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 an 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 individuals 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 that the technology results in an improvement in the net health outcome.

Ongoing and Unpublished Clinical Trials

A search of [ClinicalTrials.gov](https://clinicaltrials.gov) in March 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

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.



2011 Input

In response to requests, input was received from two physician specialty societies and three academic medical centers while this policy was under review 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

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

North American Spine Society

In 2016, the North American Spine Society issued a coverage recommendation for electrical bone growth stimulators based on a systematic review of the evidence, which stated the following¹⁴:

- "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:
 - Are undergoing spinal fusion of two or more motion segments (3 vertebrae)
 - Are undergoing a revision spinal fusion (e.g., repeat surgery for a previously unhealed fusion attempt)
 - Are smokers who cannot stop smoking in preparation for fusion due to the nature of the underlying condition (e.g., acute traumatic fracture)



- Exhibit one or more of the following comorbidities when undergoing primary lumbar fusion:
 - Diabetes
 - Inflammatory arthritis (e.g., rheumatoid arthritis) that has required long-term corticosteroid therapy
 - Immunocompromised (e.g., undergoing chemotherapy and radiation therapy to the spine, hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease)
 - Systemic vascular disease
 - Osteopenia or osteoporosis
- 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.
 - 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
 - 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

In 2014, updated guidelines from the American Association of Neurological Surgeons and the Congress of Neurological Surgeons based on a systematic review that included conflict of interest declaration, indicated that there was no evidence published after their 2005 guidelines that conflicts with the previous recommendations regarding bone growth stimulation.¹⁵

Based on a single level II study (2009), the routine use of direct current stimulation in individuals older than age 60 years was not recommended. Use of direct current stimulation was recommended as an option for individuals 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 individuals, and the overall recommendation was level C. There was insufficient evidence to recommend for or against the use of PEMFS as a treatment alternative to revision surgery in individuals presenting with pseudarthrosis following posterolateral lumbar fusion (single level IV study). No additional studies investigating the efficacy of capacitively coupled electrical stimulation were identified.

The two 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."¹⁶

Medicare National Coverage

Medicare covers noninvasive electrical stimulators for the following¹⁷:

- "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 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 (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 three or more vertebrae (e.g., L3-L5, L4-S1, etc.)."

Regulatory Status

Implantable Devices

The following implantable device was approved by the US 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) was approved.

Noninvasive Devices

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 9 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 individuals at high risk for nonfusion.
- In 2020, the ActaStim-S Spine Fusion Stimulator (Theragen, Inc.), was approved as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. This device is secured with a belt around the waist.



Semi-Invasive Devices

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

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

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History

Date	Comments
07/01/19	New policy, approved June 4, 2019. This policy numbered 7.01.571 replaces 7.01.85 which is now deleted. Policy created with literature review through February 2019; reference 23 added. Title changed to "Electrical Bone Growth Stimulation of the Spine" from "Electrical Stimulation of the Spine as an adjunct to Spinal Fusion". Electrical bone growth stimulation may be considered medically necessary when criteria are met, considered investigational for specified indications.
07/01/20	New Policy number (7.01.85), approved June 18, 2020. Policy 7.01.85 replaces policy 7.01.571 which is now deleted. Policy updated with literature review through January 2020; references updated. Removed policy statement which considered invasive, semi-invasive, and noninvasive electrical bone growth stimulation investigational as an adjunct for healing of lumbar spondylolysis. Title changed from "Electrical Bone Growth Stimulation of the Spine" to "Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures".
07/01/21	Annual Review, approved June 1, 2021. Policy updated with literature review through March 6, 2021; no references added. Policy statements unchanged.
07/01/22	Annual Review, approved June 13, 2022. Policy updated with literature review through January 17, 2022; no references added. Policy statements unchanged.
07/01/23	Annual Review, approved June 12, 2023. Policy updated with literature review through January 16, 2023; no references added. Minor editorial refinements to policy statements, intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.



Date	Comments
07/01/24	Annual Review, approved June 10, 2024. Policy updated with literature review through March 2, 2024; no references added. Policy statement unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

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