FEP Medical Policy Manual

FEP 7.01.85 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Effective Policy Date: July 1, 2022

Original Policy Date: June 2012

Related Policies:

1.01.05 - Low Intensity Pulsed Ultrasound Fracture Healing Device
7.01.07 - Electrical Bone Growth Stimulation of the Appendicular Skeleton

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

Description

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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.

OBJECTIVE

The objective of this evidence review is to determine whether the use of electrical bone growth stimulation improves bone fusion rates in individuals at risk for spinal fusion failure.

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, 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 1 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 6 months after the original surgery, as evidenced by serial radiographs over a course of 3 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 **not medically necessary** as an adjunct to cervical fusion surgery and for failed cervical spine fusion

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA 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) was approved.

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 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 patients 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.

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

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 Technology Evaluation Center (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 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 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 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 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 that the technology results in an improvement In the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

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

North American Spine Society

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 following:[14,]

1. "For augmentation of spinal fusion in any and all regions of the spine including occipital-cervical, cervical, cervicothoracic, thoracic, thoracolumbar, lumbar and lumbosacral spinal regions in patients at high-risk for the development of pseudarthrosis (ie, nonunion) who exhibit one or more of the following:
    1. Are undergoing spinal fusion of two or more motion segments (3 vertebrae)

2. Are undergoing a revision spinal fusion (eg, repeat surgery for a previously unhealed fusion attempt)
3. Are smokers who cannot stop smoking in preparation for fusion due to the nature of the underlying condition (eg, acute traumatic fracture)
4. Exhibit one or more of the following comorbidities when undergoing primary lumbar fusion:
    1. Diabetes
    2. Inflammatory arthritis (eg, rheumatoid arthritis) that has required long-term corticosteroid therapy
    3. Immunocompromised (eg, undergoing chemotherapy and radiation therapy to the spine, hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease)
    4. Systemic vascular disease
    5. 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.
    1. 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
    2. 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 on bone growth stimulation.[15,]

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 pulsed electromagnetic fields for enhancing fusion rates following PLF. Class II and III medical evidence supports the use of pulsed electromagnetic fields 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,]

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare covers noninvasive electrical stimulators for the following:[17,]

- "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)."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2012	New policy	
March 2013	Replace policy	Policy updated with literature review; added policy statement that semi-invasive stimulators are investigational.
December 2013	Replace policy	Policy updated with literature review, policy statement unchanged.
June 2017	Replace policy	Policy updated with literature review through February 23, 2017;References 5, 17, 18 added. Policy statements unchanged.
June 2018	Replace policy	Policy updated with literature review through February 14, 2018; reference 15 added. Policy statements unchanged.
June 2019	Replace policy	Policy updated with literature review through February 19, 2019; no references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 31, 2020; no references added. Policy statements unchanged.
June 2021	Replace policy	Policy updated with literature review through March 6, 2021; no references added. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through January 17, 2022; no references added. Policy statements unchanged.