The following Protocol contains medical necessity criteria that apply for this service. It is applicable to Medicare Advantage products unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Preauthorization is required. 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.

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 chances of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion.

Background

Electrical and electromagnetic fields can be generated and applied to bones through the following methods:

- Surgical implantation of a cathode at the fracture site with the production of direct current (DC) electrical stimulation. 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 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 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 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 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 a 30-minute treatment per day for nine months. Patient compliance may be an issue with externally worn devices.

- 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 devices have received U.S. Food and Drug Administration (FDA) premarket approval (PMA):

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

Noninvasive bone growth stimulators that have received FDA PMA include:
The SpinalPak® bone growth stimulator system from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a capacitive coupling system, received PMA in 1999 for use as an adjunct to primary lumbar spinal fusion at one or two levels.  
The EBI Bone Healing System® from Biolectron (a subsidiary of Electro-Biology, Inc., Parsippany, NJ) is a pulsed electromagnetic field system which was first approved in 1979 with FDA PMA and indicated for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.  
SpinaLogic Bone Growth Stimulator® (Regentek, a division of dj Orthopedics, LLC [formerly OrthoLogic, Tempe, AZ]) received PMA in 1994 as a combined magnetic field portable device. This device is secured with a belt around the waist.  
Spinal-Stim Lite® (Orthofix, Inc., Richardson, TX) received PMA in 1996 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 nine months has elapsed since the last surgery.  
The Cervical-Stim® from Orthofix, Inc., Richardson, TX is a pulsed electromagnetic field system that was approved in 2004 as an adjunct to cervical fusion surgery in patients at high risk for nonfusion. An illustration of how this particular device is worn is available at online site: http://www.orthofix.com/products/spine_cervstim.asp.  
No semi-invasive electrical bone growth stimulator devices were identified with FDA approval or clearance.

### Related Protocols

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

### Policy (Formerly Corporate Medical Guideline)

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 III or worse spondylolisthesis;  
- fusion to be performed at more than one level;  
- current tobacco use;  
- diabetes;  
- renal disease;  
- alcoholism;  
- steroid use.

Noninvasive electrical bone stimulation may be considered **medically necessary** as a treatment of patients with failed lumbar spinal fusion. 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 x-rays over a course of three months.
Semi-invasive electrical stimulation is considered **investigational** as an adjunct to lumbar fusion surgery and for failed lumbar fusion. 

Invasive, semi-invasive, and noninvasive electrical 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 (e.g., L3-L5, L4-S1, etc.).

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 (e.g., L3-L5, L4-S1, etc.).

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


