



**BlueCross BlueShield  
of Vermont**

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## Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures Corporate Medical Policy

File name: Electrical Stimulation of the Spine as an Adjunct  
to Spinal Fusion Procedures  
File code: UM.SPSVC.17  
Origination: 08/2015  
Last Review: 10/2017  
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### 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 in patients who are at normal risk of failed fusion to treat a failed fusion.

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 1 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. The evidence is insufficient to determine the effects of the technology on health outcomes.

## Policy

### Coding Information

Click the link below for attachments, coding tables & instructions.

[Attachment I - CPT® & HCPCS Code Table & Instructions](#)

## Policy Guidelines

### When a service may be considered medically necessary

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. High risk fusion failure is 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 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months.

### When a service is considered investigational

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.

### Regulatory status

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

- In 1999, the SpinalPak® bone growth stimulator system (Bioelectron, a subsidiary of ElectroBiology, Parsippany, NJ), 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, Parsippany, NJ), 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, Tempe, AZ]) 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, Richardson, TX) 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, Richardson, TX), 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 FDA approval or clearance.

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

### Reference Resources

1. Blue Cross and Blue Shield Association Medical Policy # 7.01.85. Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures
2. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation as an adjunct to spinal fusion surgery (invasive method). 1992 TEC Evaluations, pp. 324-51. PMID
3. Blue Cross and Blue Shield Association Technology Evaluation Center (TEC). Electrical bone growth stimulation in association with spinal fusion surgery (Noninvasive method). 1993 TEC Evaluations, pp. 1-12. PMID

## Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

## Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

# Administrative and Contractual Guidance

## Benefit Determination Guidance

Prior approval is required for services as outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service

department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

**Policy Implementation/Update information**

08/2015	BCBSA medical policy MPRM 7.01.85
10/2017	Aligned with BCBSA MPRM #7.01.8. Medical criteria changed to include invasive procedure language in policy statement. Literature and references reviewed. Coding Summary: removed duplicate coding table. Codes 20975 & E0749 removed from investigational to requiring PA. Removed ICD-10-CM coding table.

**Eligible providers**

Qualified healthcare professionals practicing within the scope of their license(s).

**Approved by BCBSVT Medical Directors**

**Date Approved**

Gabrielle Bercy-Roberson, MD, MPH, MBA  
 Senior Medical Director  
 Chair, Health Policy Committee

Joshua Plavin, MD, MPH, MBA  
 Chief Medical Officer

**Attachment I**  
**CPT® & HCPCS Code Table & Instructions**

Code Type	Number	Description	Policy Instructions
<b>The following codes will be considered as medically necessary when applicable criteria have been met.</b>			
CPT®	20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)	Prior Approval is required
HCPCS	E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications	Prior Approval is required
CPT®	20975	Electrical stimulation to aid bone healing; invasive (operative)	Prior Approval is required
HCPCS	E0749	Osteogenesis stimulator, electrical, surgically implanted	Prior Approval is required