Medical Policy

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

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**Policy Number:** 498

BCBSA Reference Number: 7.01.85

**Related Policies**

- Ultrasound Accelerated Fracture Healing Device, #497
- Electrical Bone Growth Stimulation of the Appendicular Skeleton, #499
- Bone Morphogenetic Protein, #097

**Policy**

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Members**

Either invasive or noninvasive methods of electrical bone growth stimulation may be **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, and
- Steroid use.

Noninvasive electrical bone stimulation may be **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.

Semi-invasive electrical stimulation is **INVESTIGATIONAL** as an adjunct to lumbar fusion surgery and for failed lumbar fusion.
Non-invasive electrical bone growth stimulation for treatments that do not meet the criteria noted above are **INVESTIGATIONAL**.

Invasive, semi-invasive, and noninvasive electrical stimulation are **INVESTIGATIONAL** as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

BCBSMA covers a spinal electrical osteogenesis stimulator following indications for Medicare HMO Blue and Medicare PPO Blue members in accordance with CMS LCD:

- Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, or
- Following a multilevel spinal fusion surgery; or
- Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site

**Local Coverage Determination (LCD) for Osteogenesis Stimulators (L11501)**

http://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCId=11501&ContrId=137&ver=33&ContrVer=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=Massachusetts&CptHcpcsCode=e0760&bc=gAAAAABAAAAAAA%3d%3d&

**Prior Authorization Information**

**Commercial Members: Managed Care (HMO and POS)**

Prior authorization is **NOT** required.

**Commercial Members: PPO, and Indemnity**

Prior authorization is **NOT** required.

**Medicare Members: HMO BlueSM**

Prior authorization is **NOT** required.

**Medicare Members: PPO BlueSM**

Prior authorization is **NOT** required.

**CPT Codes / HCPCS Codes / ICD-9 Codes**

The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (non-operative)</td>
</tr>
<tr>
<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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**HCPCS Codes**

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<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tr>
<td>E0748</td>
<td>Osteogenesis stimulator, electrical, non-invasive, spinal applications</td>
</tr>
<tr>
<td>E0749</td>
<td>Osteogenesis stimulator, electrical (surgically implanted)</td>
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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 to treat a failed fusion.

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. 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 pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. Patient compliance may be an issue with externally worn devices, and
- 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.

Examples of implantable electrical bone growth stimulators include the OsteoStim® from Electro-Biology, Inc. All implantable electrical bone growth stimulators are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy.

Examples of non-invasive bone growth stimulators the SpinalPak® bone growth stimulator system, EBI Bone Healing System® from Electrobiology, Inc and Cervical-Stim® from Orthofix. All non-invasive bone growth stimulators are considered investigational regardless of the commercial name, the manufacturer or FDA approval status except when used for the medically necessary indications that are consistent with the policy.

Summary

Evidence from RCTs suggests that electrical stimulation leads to higher fusion rates for patients undergoing lumbar surgery. Interpretation of clinical trial data is limited by the heterogeneous populations studied and the variety of surgical procedures within the populations. Most patients in these studies were at high-risk for non-fusion, suggesting that the patients most likely to benefit are those at highest risk. The policy therefore indicates that electrical stimulation of the lumbar spine, whether invasive or noninvasive, should be limited to those patients with high-risk features. For patients at average risk for non-fusion, the scientific data are inadequate to determine the magnitude of benefit associated with electrical stimulation.

At present, the evidence does not demonstrate that electrical stimulation as an adjunct to fusion of cervical vertebrae improves health outcomes. In addition, clinical input regarding the efficacy of the technology was mixed. Therefore, electrical stimulation as an adjunct to fusion of cervical spine is considered investigational.

In addition, since there are no FDA-approved semi-invasive devices, these are considered investigational.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>12/2013</td>
<td>Added LCD: L11501 to the policy</td>
</tr>
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</table>
No changes to policy statements.

No changes to policy statements.

No changes to policy statements.

Changes to policy statements.

No changes to policy statements.

Changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information:
Medical Policy Terms of Use
Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References