Electrical Bone Growth Stimulation

Description of Procedure or Service

Electrical bone growth stimulation is a medical technique to promote bone growth in difficult to heal fractures by applying a low electrical current to the fracture site. A variety of invasive and noninvasive interventions are used to treat fracture non-union including immobilization, casting, open or closed surgical reduction, pins, screw fixation, intramedullary rods and bone grafting. Bone growth stimulators, which may be non-invasive or invasive, may be used instead of, or in addition to, other interventions to promote bone healing.

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

1. 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 6 to 9 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.

2. 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 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 6–8 hours per day for 3 to 6 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 9 months. Patient compliance may be an issue with externally worn devices.

3. 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 device was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process: The OsteoStim® (Electro-Biology), which may also be marketed under the trade name SPF (Biomet).

The noninvasive OrthoPak®Bone Growth Stimulator (BioElectron) received U.S. Food and Drug
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Administration (FDA) premarket approval in 1984 for treatment of fracture nonunion. Pulsed electromagnetic field systems with FDA premarket approval (all noninvasive devices) include Physio-Stim® from Orthofix Inc., first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System® from Electrobiology, Inc., which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudoarthroses. No distinction was made between long and short bones. The FDA has approved labeling changes for electrical bone growth stimulators that remove any timeframe for the diagnosis.

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

This policy discusses the use of bone growth stimulators on the appendicular skeleton and spine.

Related Policies:
Ultrasound Accelerated Fracture Healing Devices
Bone Morphogenetic Protein
Lumbar Spine Fusion Surgery

***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.

Policy

BCBSNC will provide coverage for Electrical Bone Growth Stimulation when it is considered medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member’s Benefit Booklet for availability of benefits. Member’s benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Electrical Bone Growth Stimulation is covered

1. Non-invasive electrical bone growth stimulation may be considered medically necessary as treatment of fracture non-unions or congenital pseudoarthroses in the appendicular skeleton.

   The diagnosis of fracture non-union must meet ALL of the following criteria:

   a. at least 3 months have passed since the date of the fracture;
   b. serial radiographs for the preceding 3 month period have confirmed that no progressive signs of healing have occurred;
   c. the fracture gap is one centimeter or less; and
   d. the patient can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.

2. Invasive methods of bone growth stimulation may be considered medically necessary when used as an adjunct to surgical treatment of non-union of major long bone fractures.
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3. Either invasive or non-invasive methods of electrical bone growth stimulation may be considered medically necessary as an adjunct to lumbar spinal fusion surgery for patients with any of the following risk factors for subsequent failed fusion:
   a. one or more previous failed spinal fusion(s);
   b. grade III or worse spondylolisthesis;
   c. fusion to be performed at more than one level;
   d. current tobacco use;
   e. diabetes;
   f. renal disease;
   g. alcoholism;
   h. steroid use.

4. Non-invasive electrical bone stimulation may be considered medically necessary as a treatment for patients with failed lumbar spinal fusion. Failed spinal fusion is defined as a spinal fusion which 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 Electrical Bone Growth Stimulation is not covered

1. For any conditions or medical criteria other than those cited above.

2. Investigational applications of electrical bone growth stimulation in the appendicular skeleton include, but are not limited to:
   - immediate post-surgical treatment;
   - treatment of fresh fractures,
   - delayed union
   - arthrodesis
   - failed arthrodesis
   - stress fractures

3. Investagential applications of electrical bone growth stimulation in the spine include, but are not limited to:
   - Semi-invasive electrical bone growth stimulators as an adjunct to lumbar fusion and for failed lumbar fusion.
   - Invasive, semi-invasive, and noninvasive electrical stimulation as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

Policy Guidelines

Fresh Fractures:

A fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.

Delayed Union:

Delayed union is defined as a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity or bone reaction at the fracture site.
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**Nonunions:**

The FDA labeling simply suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the time frame of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months. The following patient selection criteria are suggested, consistent with those proposed for electrical stimulation as a treatment of nonunions:

- At least 3 months have passed since the date of the fracture, AND
- Serial radiographs have confirmed that no progressive signs of healing have occurred, AND
- The fracture gap is 1cm or less, AND
- The patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

The evidence for noninvasive electrical bone growth stimulation in individuals who have fracture nonunion includes randomized controlled trials (RCTs) and systematic reviews of clinical trials. Relevant outcomes are symptoms, change in disease status, and functional outcomes. There is evidence from these studies that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. However, the evidence is not from high-quality RCTs, and the systematic reviews provide only qualified support for this conclusion. The U.S. Food and Drug Administration has approved noninvasive electrical bone growth stimulation for the indications of fracture nonunions and congenital pseudoarthroses in the appendicular skeleton, and it is acknowledged that there are limited other options in this population. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for noninvasive electrical bone growth stimulation in individuals who have delayed union, fresh or stress fractures, or who have had surgery of the appendicular skeleton includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Two RCTs found no benefit of electrical bone growth stimulation for fresh fractures. RCTs on delayed union of the other types of fractures were limited by small sample size and did not show a significant difference between study groups. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for invasive or noninvasive electrical bone growth stimulation in individuals who are at high risk of lumbar spinal fusion failure includes a TEC Assessment and randomized controlled trials (RCTs). Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials indicate 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 qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for noninvasive electrical bone growth stimulation in individuals who are at normal risk for lumbar spinal fusion failure includes RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Several RCTs have shown increased fusion rates with noninvasive bone stimulation in patient populations that include both high risk and normal risk groups. No studies were identified that studied a population of patients who were all at normal risk for fusion failure. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for noninvasive electrical bone growth stimulation in individuals who have failed lumbar spinal fusion includes a TEC Assessment and studies where patients served as their own controls. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Data indicate that noninvasive electrical stimulation improves the fusion rate in this population. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for invasive or noninvasive electrical bone growth stimulation in individuals who are undergoing cervical spinal fusion surgery or who have failed cervical spine fusion includes an RCT.
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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.

NOTE: Patients with implanted electronic devices should consult their physician before using these electrical bone growth stimulation devices.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: 20974, 20975, E0747, E0748, E0749

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Consultant Review - 8/94


FDA Approval letter dated 6/12/98


Consultant Review - 3/99


Medical Policy Advisory Group - 12/2/1999


Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion Fractures (September
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Foley KT, Mroz TE, Arnold PM et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. Spine J 2008; 8(3):436-42


Specialty Matched Consultant Advisory Panel review 7/2010


Specialty Matched Consultant Advisory Panel review 7/2011


Specialty Matched Consultant Advisory Panel review 7/2012


Medical Director review 10/2012

Specialty Matched Consultant Advisory Panel review 7/2013

Medical Director review 7/2013


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Specialty Matched Consultant Advisory Panel review 7/2014
Medical Director review 7/2014


Specialty Matched Consultant Advisory Panel review 6/2015


**Policy Implementation/Update Information**

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<tr>
<td>4/81</td>
<td>Original Policy</td>
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<tr>
<td>11/81</td>
<td>Reaffirmed</td>
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<td>12/83</td>
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<tr>
<td>5/99</td>
<td>Medical Policy Advisory Group</td>
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<tr>
<td>7/99</td>
<td>Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.</td>
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<tr>
<td>12/99</td>
<td>Reaffirmed, Medical Policy Advisory Group</td>
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<tr>
<td>2/01</td>
<td>System coding changes.</td>
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<tr>
<td>6/01</td>
<td>Removed &quot;The presence of iron-containing internal fixation devices in the area to be stimulated.&quot; from When Electrical Bone Growth Stimulation is Not Covered section of the policy. Coding format change. E0760 removed from coding.</td>
</tr>
<tr>
<td>5/03</td>
<td>Specialty Matched Consultant Advisory Panel review. Revised under &quot;when it is covered&quot; section, number 1.b., changed the term &quot;non-progressive&quot; to &quot;no progressive&quot;. Code E0760 removed from the Billing/Coding section.</td>
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<tr>
<td>3/04</td>
<td>Benefits Application and Billing/Coding sections updated for consistency.</td>
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<tr>
<td>8/26/04</td>
<td>Code descriptions removed. References added. Definition for non-union corrected in Medical Terms and definition for delayed union added.</td>
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6/18/07 Routine biennial review. Information added to Description for clarity. Specialty Matched Consultant Advisory Panel review 5/18/07. No changes to policy coverage criteria. (adn)

7/20/09 Routine biennial review. Specialty Matched Consultant Advisory Panel review 5/21/09. No change to policy statement. (adn)

8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Removed Medical Policy number. Updated references. Updated the “Policy Guidelines” section. Existing medically necessary policy statements modified by adding lumbar (spine) to the statements. Steroid use added as another high-risk condition for non-fusion. Added the following criteria to “When Not Covered” section: “3. Implantable and semi-invasive electrical bone growth stimulators are considered investigational. 4. Invasive, semi-invasive, and noninvasive electrical stimulation are considered investigational as an adjunct to cervical fusion surgery and for failed cervical spine fusion.” (mco)


11/8/11 References updated. No changes to Policy Statements. (mco)

8/7/12 Specialty Matched Consultant Advisory Panel review 7/2012. No changes to Policy Statements. (mco)

11/27/12 Added related policy to Description section. Revised the following statement in the “When not Covered” section: “2. Investigational applications of electrical bone growth stimulation in the appendicular skeleton include, but are not limited to, immediate post-surgical treatment, and treatment of fresh fractures, delayed union or failed arthrodesis. Delayed union is defined as a decelerating fracture healing process, as identified by serial x-rays. 3. Semi-invasive electrical bone growth stimulators are considered investigational as an adjunct to lumbar fusion and for failed lumbar fusion.” References updated. Medical Director review. Policy noticed on 11/27/12 for effective date 2/26/13. (mco)


11/26/13 References updated. No changes to Policy Statements. (mco)

2/25/14 Description section updated. Policy Guidelines and References updated. Use of electrical bone growth stimulation for stress fractures and arthrodesis added to “When not Covered” section. “When Covered” section updated to include the following criterion: “The patient can be adequately immobilized and is of an age likely to comply with non-weight bearing for fractures of the pelvis and lower extremities.” Medical Director review 2/2014. Policy noticed on 2/25/14 for effective date 4/29/14. (mco)


1/27/15 Reference added. Related policies added. (sk)

2/24/15 Reference added. (sk)


5/31/16 References added. Policy Guidelines updated. (sk)

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Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.