

Corporate Medical Policy

Electrical Bone Growth Stimulation

File Name: electrical_bone_growth_stimulation
Origination: 4/1981
Last CAP Review: 7/2011
Next CAP Review: 7/2012
Last Review: 7/2011

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.

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

******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.***

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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.
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.
 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 smoking habit;
 - 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

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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 include, but are not limited to, the treatment of fresh fractures or delayed union. 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.
4. Invasive, semi-invasive, and noninvasive electrical stimulation are considered investigational as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

Policy Guidelines

Interpretation of clinical trial data is limited by the heterogeneous populations studied, and the variety of surgical procedures within the populations. The policy indicates that electrical stimulation, whether invasive or noninvasive, should be limited to those patients with high-risk features. A review of the literature suggests that the patients most likely to benefit are those at highest risk. In addition, electrical stimulation may improve the fusion rate in patients undergoing both instrumented and non-instrumented surgeries. However, scientific data are inadequate to determine the magnitude of benefit associated with electrical stimulation in patients considered at average risk for fusion failure.

At present, the evidence is insufficient that electrical stimulation as an adjunct to fusion of cervical vertebrae improves fusion rates or functional outcomes.

No semi-invasive electrical bone growth stimulator devices have received FDA approval or clearance at this time, therefore they are considered investigational.

NOTE: Patients with cardiac pacemakers should consult their cardiologist before using these 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

BCBSA Medical Policy Reference Manual - 12/95

FDA Approval letter dated 6/12/98

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BCBSA Medical Policy Reference Manual - 9/23/98

Consultant Review - 3/99

Medical Policy Advisory Group - 5/99

Specialty Matched Consultant Advisory Panel - 11/1999

Medical Policy Advisory Group - 12/2/1999

Specialty Matched Consultant Advisory Panel - 8/2001

BCBSA Medical Policy Reference Manual - 12/18/2002; 7.01.07

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 12/17/03

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 02/25/04

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 3/07/06

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 3/15/05

Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program. The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion Fractures (September 2005). Retrieved 2/16/07 from <http://www.cms.hhs.gov/coverage/download/id30M.pdf>

Centers for Medicare and Medicaid Services. NCD for Osteogenic Stimulators, Manual Section Number 150.2. Retrieved 2/19/07 from http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=150.2&ncd_version=2&basket=ncd%3A150%2E2%3A2%3AOsteogenic+Stimulators

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 2/14/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 8/14/08

Kooistra BW, Jain A, Hanson BP. (April 2009). Electrical Stimulation: Non-Unions. Indian J Orthop, 43(2), 149-155. Retrieved on May 12, 2010 from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2762246/?tool=pubmed>

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 9/10/09

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 9/10/09

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BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.85, 9/16/10

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 9/16/10

Griffin XL, Costa ML, Parsons N, Smith N. Electromagnetic field stimulation for treating delayed

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union or non-union of long bone fractures in adults. Cochrane Database of Systematic Reviews 2011, Abstract. Retrieved on June 20, 2011 from <http://onlinelibrary.wiley.com/o/cochrane/clsysrev/articles/CD008471/frame.html>

Specialty Matched Consultant Advisory Panel review 7/2011

BCBSA Medical Policy Reference Manual [Electronic Version]. 7.01.07, 9/1/11

Policy Implementation/Update Information

- 4/81 Original Policy
- 11/81 Reaffirmed
- 12/83 Reaffirmed
- 5/99 Medical Policy Advisory Group
- 7/99 Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 12/99 Reaffirmed, Medical Policy Advisory Group
- 2/01 System coding changes.
- 6/01 Removed "The presence of iron-containing internal fixation devices in the area to be stimulated." from When Electrical Bone Growth Stimulation is Not Covered section of the policy. Coding format change. E0760 removed from coding.
- 10/01 Specialty Matched Consultant Advisory Panel - 8/01. No changes.
- 5/03 Specialty Matched Consultant Advisory Panel review. Revised under "when it is covered" section, number 1.b., changed the term "non-progressive" to "no progressive". Code E0760 removed from the Billing/Coding section.
- 3/04 Benefits Application and Billing/Coding sections updated for consistency.
- 8/26/04 Code descriptions removed. References added. Definition for non-union corrected in Medical Terms and definition for delayed union added.
- 6/2/2005 Specialty Matched Consultant Advisory Panel review on 5/23/2005. No changes made to the policy statement. SUR6240 added as key word.
- 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)

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8/16/11 Description section updated. References updated. Specialty Matched Consultant Advisory Panel review 7/2011. No changes to policy statements. (mco)

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

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.