Medical Coverage Policy | Electrical Bone Growth Stimulation

EFFECTIVE DATE: 08|01|2000
POLICY LAST UPDATED: 10|01|2013

OVERVIEW

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 spinal fusion.

In the appendicular skeleton, electrical stimulation (with either implantable electrodes or noninvasive surface stimulators) has been investigated for the treatment of delayed union, nonunion, and fresh fracture

PRIOR AUTHORIZATION

Prior Authorization is required for BlueCHiP for Medicare members and recommended for all other BCBSRI products.

POLICY STATEMENT

Appendicular Skeleton:

BlueCHiP for Medicare:

Invasive and non- invasive electrical bone growth stimulation devices are medically necessary when the below criteria is met.

Commercial:

Non-invasive electrical bone growth stimulator is medically necessary when the below criteria is met.

Invasive is considered not medically necessary as there is insufficient peer reviewed scientific literature that demonstrates that the procedure/service is effective.

BC for Medicare and Commercial

- Semi invasive is not covered as there is not an FDA approved device
- Use of electrical bone growth stimulator as a treatment of, stress fractures or any treatment to sesamoid bones is considered not medically necessary as there is insufficient peer-reviewed scientific literature that demonstrates the procedure/service is effective.

Adjunct to Spinal fusion

BlueCHiP for Medicare and Commercial:

Invasive and non-invasive electrical bone growth stimulators are medically necessary for failed spinal fusion when the below criteria is met.

Commercial

Invasive and non-invasive electrical stimulation is not medically necessary as an adjunct to Cervical fusion or failed cervical spine surgery as there is insufficient peer reviewed scientific literature that demonstrates that the procedure/service is effective.

BlueCHiP for Medicare and Commercial:

Semi invasive is not covered as there is not an FDA approved device

MEDICAL CRITERIA

Appendicular skeleton

Noninvasive electrical bone growth

BlueCHiP for Medicare

Noninvasive electrical bone growth stimulation may be considered medically necessary as a treatment of nonunion long bone fractures or congenital psuedoarthroses in the appendicular skeleton. The diagnosis of fracture nonunion must meet all of the following criteria:

- Serial radiografts have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical stimulator and
- Serial radiografts must include a minimum of 2 sets of radiografts, each including multiple views of the fracture site and
- Serial radiografts must be seperated by a minimum of 90 days

Commercial Products

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as treatment of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton. The diagnosis of fracture nonunion must meet ALL of the following criteria:

- at least 3 months have passed since the date of fracture;
- serial radiographs have confirmed that no progressive signs of healing have occurred;
- the fracture gap is 1 cm or less; and
- the patient can be adequately immobilized and is of an age likely to comply with non-weight bearing.

Invasive electrical bone growth

BlueCHiP for Medicare

Invasive electrical bone growth stimulation is considered **medically necessary** in the treatment of nonunion of long bone fractures when all of the criteria are met **.**

The diagnosis of long bone fracture nonunion is considered to exist only:

- Serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the **invasive** electrical bone growth stimulator, **and**
- Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Adjunct To Spinal Fusion:

BlueCHiP for Medicare

Noninvasive

BlueCHiP for Medicare covers noninvasive electrical stimulators for the following when one of the following criteria are met:

- Failed fusion, where a minimum of 9 months has elapsed since the last surgery
- As an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site
- adjunct to those undergoing multiple level fusion. A multiple level fusion involves three or more vertebrae (e.g., L3-L5, L4-S1, etc.).

Invasive

BlueCHiP for Medicare covers invasive electrical stimulators

- 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.).

Commercial Products

Invasive or Noninvasive -

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, **when one of the following criteria is met:**

- 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.

BACKGROUND

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 spinal fusion.
In the appendicular skeleton, electrical stimulation (with either implantable electrodes or noninvasive surface stimulators) has been investigated for the treatment of delayed union, nonunion, and fresh fractures.

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 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.
- Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using 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 over 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.
- 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.

Appendicular:

In the appendicular skeleton, electrical stimulation has been used primarily to treat tibial fractures, and thus this technique has often been thought of as a treatment of the long bones. According to orthopedic anatomy, the skeleton consists of long bones, short bones, flat bones, and irregular bones. Long bones act as levels to facilitate motion, while short bones function to dissipate concussive forces. Short bones include those composing the carpus and tarsus. Flat bones, such as the scapula or pelvis, provide a broad surface area for attachment of muscles. Despite their anatomic classification, all bones are composed of a combination of cortical and trabecular (also called cancellous) bone. Each bone, depending on its physiologic function, has a different proportion of cancellous to trabecular bone. At a cellular level, however, both bone types are composed of lamellar bone and cannot be distinguished microscopically.

There is evidence from randomized controlled trials RCTs and systematic reviews of clinical trials that noninvasive electrical stimulators improve fracture healing for patients with fracture non-union. This evidence is not from high-quality RCTs; however, and systematic reviews provide qualified support for this conclusion. Based on the available evidence and the lack of other options for patients with non-union, electrical stimulation may be considered medically necessary for the U.S. Food and Drug Administration (FDA)-approved indications of fracture nonunions or congenital pseudoarthroses in the appendicular skeleton when the specific criteria listed below is met.

There is insufficient evidence to evaluate the efficacy of noninvasive electrical bone growth stimulation following surgery of the appendicular skeleton or for the treatment of delayed union. In addition, a recent randomized trial found no benefit of electrical bone growth stimulation for fresh fractures. Use of

noninvasive electrical bone growth stimulation for these conditions is considered not medically necessary as there is no proven efficacy.

Evidence is insufficient to evaluate health outcomes with use of electrical bone growth stimulator as a treatment of, including, but not limited too, stress fractures or any treatment to **sesamoid bones**. Use of electrical bone growth stimulator for these conditions is considered not medically necessary as there is no proven efficacy.

The literature for implantable bone stimulators of the appendicular skeleton consists of a small number of case series, therefore, invasive bone growth stimulators are considered not medically necessary as there is no proven efficacy.

In addition, no semi-invasive devices have FDA clearance or approval, since there are no FDA-approved semi-invasive devices, these are considered not covered.

Adjunct to Spinal Fusion:

Evidence from randomized controlled trials (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. 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 is inadequate to determine the magnitude of benefit associated with electrical stimulation therefore, is considered not medically necessary as there is no proven efficacy.

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 not medically necessary as there is no proven efficacy.

In addition, no semi-invasive devices have FDA clearance or approval, since there are no FDA-approved semi-invasive devices, these are considered not covered.

Definitions

Fresh Fracture

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 for no less than 3 months from the index injury or the most recent intervention.

Nonunion
There is not a consensus for the definition of nonunions. One proposed definition is failure of progression of fracture-healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing).

Appendicular Skeleton
The appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities.

COVERAGE

Benefits may vary between groups/contracts. Please refer to the appropriate evidence of coverage, subscriber agreement, or benefit booklet for applicable surgery services and medical equipment,/medical supplies coverage/benefits..

CODING

BlueCHiP for Medicare and Commercial:
The following codes require prior authorization:

Covered and separately reimbursed under the surgery benefit:
20975
E0749

Covered under the durable medical equipment benefit:
E0747
E0748

The following code is a covered service but **not separately reimbursed**. The manufacturer is responsible for the measuring, fitting, and application of the bone growth stimulator:
20974

RELATED POLICIES

Ultrasound Accelerated Fracture Healing Therapy

PUBLISHED

Provider Update	Dec 2013
Provider Update	Sept 2012
Provider Update	Aug 2011
Provider Update	Sept 2010
Provider Update	Nov 2009
Provider Update	Feb 2009
Policy Update	Dec 2007
Policy Update	Feb 2007
Policy Update	Dec 2006
Policy Update	July 2000

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National Institute for Health and Clinical Excellence. Low-intensity pulsed ultrasound to promote fracture healing. 2010. Available online at: http://www.nice.org.uk/nicemedia/live/12408/52076/52076.pdf

Centers for Medicare and Medicaid Services. National Coverage Decision for Osteogenic Stimulators (150.2) 2005. Available online at:

http://www.cms.hhs.gov/mcd/viewncd.asp?ncd_id=150.2&ncd_version=2&basket=ncd%3A150%2E2%3A2%3AOsteogenic+Stimulators

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Kucharzyk DW. A controlled prospective outcome study of implantable electrical stimulation with spinal instrumentation in a high-risk spinal fusion population. Spine (Phila Pa 1976) 1999; 24(5):465-8; discussion 69.

Rogozinski A, Rogozinski C. Efficacy of implanted bone growth stimulation in instrumented lumbosacral spinal fusion. Spine (Phila Pa 1976) 1996; 21(21):2479-83.

Andersen T, Christensen FB, Egund N et al. The effect of electrical stimulation on lumbar spinal fusion in older patients: a randomized, controlled, multi-center trial: part 2: fusion rates. Spine (Phila Pa 1976) 2009; 34(21):2248-53.