

Medical Coverage Policy



**Blue Cross
Blue Shield**
of Rhode Island

Electrical Bone Growth Stimulation

Device/Equipment Drug Medical Surgery Test Other

Effective Date:	1/1/2007	Policy Last Updated:	7/17/2012
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Prospective review is recommended/required. Please check the member agreement for preauthorization guidelines.

Prospective review is not required.

Description:

Electrical stimulation to augment bone repair can be attained either invasively or non-invasively.

Non-invasive bone growth stimulators:

Non-invasive bone growth stimulators use pulsed-electromagnetic fields, capacitive coupling or combined magnetic fields to generate a weak electric current through the target site. Non-invasive bone growth stimulators are used to treat fracture nonunion or congenital pseudoarthrosis in the appendicular skeleton, failed fusion after spinal fusion surgery, or as an adjunct to spinal fusion surgery in patients considered high risk for fusion failure, defined below.

Invasive bone growth stimulators:

Invasive bone growth stimulators require surgical implantation of a direct current generator in an intramuscular or subcutaneous space while an electrode is implanted within the fragments of bone graft at the fusion site. Invasive bone growth stimulation is also used as an adjunct to spinal fusion surgery in patients considered high risk for fusion failure, and is implanted at the time of surgery. Invasive bone growth stimulation is not often used in the appendicular skeleton.

Medical Criteria:

Prior authorization is required for BlueCHiP for Medicare and recommended for all other lines of business.

Medically necessary for all product lines:

Non-invasive bone growth stimulators:

Non-invasive electrical bone growth stimulation is considered medically necessary in the treatment of **fracture nonunion or congenital pseudarthrosis in the appendicular skeleton** (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities) and in the treatment of patients with failed joint fusion and failed spinal fusion*.

The diagnosis of **fracture nonunion** must meet **ALL** of the following **criteria**:

1. At least 3 months have passed since the date of fracture; **AND**
2. Serial radiographs have confirmed that no progressive signs of healing have occurred; **AND**
3. The fracture gap is one centimeter or less; **AND**
4. The patient can be adequately immobilized and is of an age where likely to comply with non-weight bearing (or as appropriate).

*The diagnosis of failed joint or failed spinal fusion is:

- a joint fusion or spinal fusion that has not healed at a minimum of 6 months after the original surgery, **AND**
- evidenced by serial X-rays over a course of 3 months (including one before or after 6 months).

Noninvasive electrical bone stimulation may be considered **not 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.

Invasive or non-invasive bone growth stimulators:

Either invasive or non-invasive methods of electrical bone growth stimulation is considered medically necessary as an **adjunct to spinal fusion** to prevent failure in a **high risk patient**, defined by any **one** of the following criteria:

1. Any previously failed spinal fusion(s); or
2. Grade III or worse spondylolisthesis; or
3. Fusion performed at more than one level; or
4. Current smoking habit; or
5. Diabetes; or
6. Renal disease; or
7. Alcoholism; or
8. Steroid use.

Invasive bone growth stimulators:

Invasive electrical bone growth stimulation is considered **medically necessary** in the treatment of **nonunion of long bone fractures**.

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

1. After 6 or more months have elapsed without healing of the fracture, **AND**
2. 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**
3. 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.

Not medically necessary for all product lines:

- Semi-invasive electrical stimulation is considered **not medically necessary** as an adjunct to lumbar fusion surgery and for failed lumbar fusion.
- Invasive, semi-invasive, and noninvasive electrical stimulation are considered **not medically necessary** as an adjunct to cervical fusion surgery and for failed cervical spine fusion.
- All other applications of electrical bone growth stimulation are considered **not medically necessary** as there is insufficient peer reviewed, scientifically controlled studies in the literature which demonstrate the superior health outcome of this treatment. They include, but are not limited to, the treatment of fresh fractures, stress fractures, and delayed union. Delayed union of a fracture is defined as a decelerating fracture healing process, identified by serial X-rays.

Policy:

Non-invasive and invasive electrical growth stimulation is considered medically necessary when the **specific** medical criteria noted above are met.

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, and prosthetic devices coverage/benefits.

Coding:

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

The following codes are covered under the member's surgical benefit:

20975

E0749

The codes listed below are covered under the member's medical equipment, medical supplies, and prosthetic devices benefit:

E0747

E0748

Also Known As:

Bioelectron Orthopak (Capacitative coupling)

EBI Model: SpF Spinal Fusion Stimulator (implantable) (Direct current)

EBI Model: OsteoGen (implantable) (Direct current)

OrthoLogic

Orthofix AME PhysioStim

Related Topics:

Ultrasound accelerated fracture healing therapy

Published:

Policy Update, July 2000

Policy Update, December 2006

Policy Update, February 2007

Policy Update, December 2007

Provider Update, February 2009

Provider Update, November 2009

Provider Update, September 2010

Provider Update, August 2011

Provider Update, May 2012

Provider Update, September 2012

References:

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Aaron RK, Ciombor DM, Simon BJ. *Treatment of nonunions with electric and electromagnetic fields*. Clinical orthopaedics and related research;2004;(419):21-9.

Blue Cross Blue Shield Association Medical Policy Reference. Policy 7.01.07 - Electrical Bone Growth Stimulation of the Appendicular Skeleton. Reviewed with literature search/September 2009.

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De Haas WG, Watson J, Morrison DM. *Non-Invasive Treatment of Ununited Fractures of the Tibia Using Electrical Stimulation*. The Journal of Bone and Joint Surgery;1980;62-B(4):465-470.

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Tajali SB, MacDermid JC, Houghton P, Grewal R. *Effects of low power laser irradiation on bone healing in animals: a meta-analysis*. Journal of Orthopaedic Surgery and Research; 2010;5:1.

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