Bone Growth Stimulators

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Description
Bone growth stimulation is utilized to promote bone healing in difficult to heal fractures or fusions by applying electrical or ultrasonic current to the fracture/fusion site. Electrical stimulation can be applied either from the outside of the body (noninvasive) or from the inside of the body (invasive).

Noninvasive (external) electrical bone growth stimulators are devices worn on the outside of the skin. They utilize treatment coils situated externally around the fracture or fusion site and an external power supply. There are three types of noninvasive electrical bone growth stimulators:

- Capacitive coupling (CC) devices – CC devices use metal electrodes, which are applied to the skin to deliver the current. An example of a CC device includes, but
may not be limited to the EBI OrthoPak® 2 Bone Growth Stimulator.

- Pulsed electromagnetic field (PEMF) devices – PEMF devices use an externally applied coil to deliver the current, which can be pulsed on and off. Examples of PEMF devices include, but may not be limited to the EBI Bone Healing System®, the Orthofix Cervical-Stim, the Orthofix Physi-Stim, the Orthofix Spinal-Stim and the SpinalPak® II Spinal Fusion Stimulator.

- Combined magnetic field (CMF) devices – CMF devices use an external coil system with a combination of direct and alternating current to produce both static and alternating magnetic fields. Examples of CMF devices include, but may not be limited to the OrthoLogic (OL) 1000 Bone Growth Stimulator and the SpinaLogic® Bone Growth Stimulator.

The surgically implanted or **invasive electrical bone growth stimulators** utilize direct current to the nonhealing fracture or bone fusion site. Examples of invasive (implantable) electrical bone growth stimulators include but are not limited to the following: the EBI OsteoGen™ Bone Growth Stimulator, the OsteoGen™ Dual Lead Bone Growth Stimulator, the OsteoGen™-M Bone Growth Stimulator, the SpF® PLUS-Mini Spinal Fusion Stimulator, the SpF®-XL IIb Spinal Fusion Stimulator, and the Zimmer Direct Current Bone Growth Stimulator.

**Ultrasonic** fracture healing utilizes a signal generator and a transducer, which when placed over the fracture site on the skin, emits low intensity ultrasound signals that are emitted directly to the fracture. Examples of ultrasonic bone growth stimulators include, but may not be limited to the Exogen 4000+™, Exogen 3000™, Exogen 2000+™, and Exogen 2000™ (also known as the SAFHS® Model 2000 or the Exogen™ Pulsed Low-Intensity Ultrasound Bone Healing System Model 2000).
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**Coverage Determination**

**Noninvasive Electrical Bone Growth Stimulator**

Humana members may be eligible under the Plan for the use of a noninvasive electrical bone growth stimulator ONLY when the following criteria are met:

- Non-union of long bone* fracture and **ALL** of the following:
  - The bone is non-infected; **AND**
  - The two portions of the bone involved in the non-union are separated by less than 1 centimeter (cm); **AND**
  - The bone is stable at both ends by means of a cast or fixation; **AND**
  - When serial radiographs (x-rays) have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the noninvasive electrical bone growth stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days; **OR**

- Failed fusion, where a minimum of six months has elapsed since the last surgery; **OR**

- As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed fusion surgery or for those undergoing fusion at more than one level; **OR**

- Congenital pseudoarthrosis; **OR**

- Risk of delayed or non-union of fractures due to the following comorbidities (list may not be all inclusive):
  - Alcoholism
  - Chemotherapy
  - Diabetes
  - Obesity

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- Osteoporosis
- Renal disease
- Smoking habit
- Steroid use

*Long bones are primarily found in the extremities and are comprised of a shaft (diaphysis) and two ends (epiphysis). Long bones, which are not straight but slightly curved, include the clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpals, metatarsals, and phalanges.

**Invasive Electrical Bone Growth Stimulator**

Humana members may be eligible under the Plan for the use of an **invasive electrical bone growth stimulator ONLY** when the following criteria are met:

- Non-union of long bone* fracture and **ALL** of the following:
  - The bone is non-infected; **AND**
  - The two portions of the bone involved in the non-union are separated by less than 1 cm; **AND**
  - The bone is stable at both ends by means of a cast or fixation; **AND**
  - When serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the invasive bone growth stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days; **OR**
- As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed fusion surgery or for those undergoing fusion at more than one level; **OR**
- Risk of delayed or non-union of fractures due to the following comorbidities (list

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may not be all inclusive):

- Alcoholism
- Chemotherapy
- Diabetes
- Obesity
- Osteoporosis
- Renal disease
- Smoking habit
- Steroid use

**Ultrasonic Bone Growth Stimulator**

Humana members may be eligible under the Plan for the use of an ultrasonic (US) bone growth stimulator when the following criteria are met:

- Fresh*, closed or grade I** open, short oblique or short spiral tibial diaphyseal fractures treated with closed reduction and cast immobilization in skeletally mature patients***; OR

- Fresh*, closed fractures of the distal radius (Colles’ fracture) treated with closed reduction and cast immobilization in skeletally mature patients***; OR

- Fresh* Jones fracture (5th metatarsal); OR

- Fresh* fractures of the scaphoid; OR

- Nonunion of bones other than the skull or vertebrae in skeletally mature patients***, and excluding those that are related to malignancy when:

  - Serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the ultrasonic bone growth stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days; AND

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Bone Growth Stimulators

- The patient has failed ≥ 1 surgery and other medical therapies; OR
- Risk of delayed or non-union of ANY fresh*, closed fractures due to the following comorbidities (list may not be all inclusive):
  - Alcoholism
  - Chemotherapy
  - Diabetes
  - Obesity
  - Osteoporosis
  - Renal disease
  - Smoking habit
  - Steroid use

*Fresh is considered ≤ 7 days in duration.

**Grade I denotes that the skin opening is one centimeter or less and minimal muscle contusion.

***Skeletally mature refers to a system of fused skeletal bones, which occurs when bone growth ceases after puberty; for females, this generally occurs around age 16, and for males, around age 18.

Note: This criteria for bone growth stimulators is not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS web site at [http://www.cms.hhs.gov](http://www.cms.hhs.gov) for additional information.

Coverage Limitations

Humana members may NOT be eligible under the Plan for the use of noninvasive or invasive electrical bone growth stimulators for any other indications not listed above. This technology is considered experimental/investigational or NOT medically necessary if it is not utilized in accordance with nationally recognized standards of medical practice and/or identified as safe, widely used and generally accepted as effective for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

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Humana members may NOT be eligible under the Plan for the use of ultrasonic bone growth stimulators for any other indications, which include, but may not be limited to:

- Fractures in which the gap exceeds 1 cm; OR
- Fresh fractures in locations other than distal radius, tibial diaphysis, 5th metatarsal (Jones fracture only) or scaphoid; OR
- Fresh tibial diaphyseal or tibial and fibular fractures treated with closed reduction and intramedullary nailing and no risk factors for poor or prolonged healing; OR
- Preoperative use for fractures that require surgical intervention, or internal or external fixation (i.e., use of ultrasonic BGS for fractures in the preoperative period would not be covered); OR
- Tibial stress fractures.

This technology is considered experimental/investigational or NOT medically necessary if it is not utilized in accordance with nationally recognized standards of medical practice and/or identified as safe, widely used and generally accepted as effective for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

Humana members may NOT be eligible under the Plan for bone growth stimulators for spondylolysis (pars interarticularis defect) or fractures due to osteoporosis. This technology is considered experimental/investigational as it is not identified as widely used and generally accepted for the proposed use as reported in nationally recognized peer-reviewed medical literature published in the English language.

**Background**

You can learn more about fractures and spinal fusions from the following sites:
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- American Academy of Orthopaedic Surgeons - [http://www.aaos.org](http://www.aaos.org)

### Medical Alternatives

To make the best health decision for your individual needs, consult your physician.

### Provider Claims Codes

All provider claims codes surrounding this topic may not be included in the following table:

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<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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<td>Osteogenesis stimulator, low intensity ultrasound, noninvasive</td>
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<td>Insertion of bone growth stimulator into humerus</td>
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<td>78.93</td>
<td>Insertion of bone growth stimulator into radius and ulna</td>
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<tr>
<td>78.94</td>
<td>Insertion of bone growth stimulator into carpals and metacarpals</td>
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### Medical Terms

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<td>78.99</td>
<td>Insertion of bone growth stimulator into other bone</td>
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<td>99.86</td>
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- **Adjunct** - Something added to another thing but not essential to it.
- **Clavicle** - Collarbone.
- **Closed Reduction** - Physical manipulation of a joint or bone externally (without making a surgical excision) to affect a joint relocation or more proper anatomic alignment of broken bone fragments.
- **Colles’ Fracture** - Fracture of the lower end of the radius in which the lower fragment is displaced posteriorly.
- **Comorbidities** - Co-existing or additional diseases with reference to an initial diagnosis.
- **Compression** - Increasing physical pressure on a vital structure.
- **Congenital** - Pertaining to a condition present at birth, whether inherited or caused by environment, especially the uterine environment.
- **Contusion** - Injury in which the skin is not broken; a bruise.
- **Diabetes** - Disease in which the body does not produce or properly use insulin, a substance that is needed to convert sugar, starches, and other food into energy.
- **Diaphysis** - Shaft of a long bone.
- **Distal** - Located away from the center of the body.
Electrode - Electrical lead or wire through which current may flow in and out.

Electromagnetic - Pertains to or produced by magnetism, which is developed by the passage of an electrical current.

External - On the outside; in this case, on the skin.

Extremities - Lower or upper limb, such as the leg or arm.

Femur - Large bone in the thigh that articulates with the pelvis above and the knee below.

Fibula - Outer and narrower of two bones of the human lower leg, extending from the knee to the ankle.

Fracture - Broken bone.

Fusion - Correction of an unstable part of the spine by joining two or more vertebrae.

Generator - Machine that converts one form of energy into another.

Humerus - Bone of the upper part of the arm or fore limb.

Intramedullary - Within the bone marrow.

Invasive - Involving puncture or incision of the skin or insertion of an instrument or foreign material into the body.

Jones Fracture - A fracture at the base of the fifth metatarsal.

Malignant - Usually used interchangeably with the term cancer, but also describes a clinical course that progresses rapidly to death.

Metacarpals - Five cylindrical bones extending from the wrist to the fingers.

Metatarsals - Five cylindrical bones extending from the heels to the toes.
Non-Invasive - Not breaking the surface of the skin.

Oblique Fracture - A fracture, the line of which runs obliquely to the axis of the bone.

Obliquely - Having a slanting or sloping direction.

Osteoporosis - Reduction in the amount of bone mass, leading to fractures after minimal trauma.

Phalanges - Finger bones.

Pseudoarthrosis - Formation of a false joint caused by the failure of the bones to fuse.

Radius - One of two bones that constitute the forearm.

Renal Disease - A disorder involving the kidneys.

Scaphoid - One of the small bones of the wrist, located on the thumb side.

Semi-Invasive - Refers to a minimal breach of the skin.

Serial - Of, pertaining to, consisting of, or occurring in a series rather than simultaneously.

Spinal Fusion - Procedure that involves fusing together two or more vertebrae in the spine using either bone grafts or metal rods.

Spiral Fracture - A fracture, the line of which is helical in the bone.

Spondylolysis - A defect in the pars interarticularis (a bone connecting one facet joint to another).

Static - Acting by mere weight without producing motion.

Steroid - Type of drug used to relieve swelling and inflammation; also all of the natural

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sex hormones are steroids.

**Stress Fracture** - Small, incomplete fracture of a bone that occurs without apparent injury as a result of overuse or excessive/repeated stress.

**Tibia** - Refers to the long bone between the knee and foot.

**Transducer** - Device that transforms one type of energy to another.

**Ulna** - One of the two bones that constitute the forearm.

**Ultrasound** - Use of high frequency sound waves; may be used in an imaging technique or for therapeutic treatment of soft tissue (or in this case, bone) injuries.

**Vertebrae** - Any of the bones or segments composing the spinal column.

### References


December 6, 2011.


UpToDate® Website. Subacute and chronic low back pain: surgical treatment.
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