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

• **Pulsed electromagnetic field (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** 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 BGS** utilize direct current to the nonhealing fracture or bone fusion site. Examples of invasive (implantable) electrical bone growth stimulators include, but may not be limited to, 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).

**Coverage Determination**

**NONINVASIVE ELECTRICAL BONE GROWTH STIMULATOR**

Humana members may be eligible under the Plan for the use of a **noninvasive electrical BGS** when the following criteria are met:

- Nonunion of a long bone* fracture and **ALL** of the following:
  - Bone is noninfected; **AND**

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Bone is stable at both ends by means of a cast or fixation; AND

The two portions of the bone involved in the nonunion are separated by less than 1 centimeter (cm); AND

X-rays at least 90 days post fracture show evidence of nonhealing or nonunion; OR

- Nonspinal failed fusion when a minimum of six months has elapsed since the initial surgery; OR

- As an adjunct to spinal fusion surgery for individuals at high risk of pseudoarthrosis due to either of the following:
  - Previously failed spinal fusion surgery; OR
  - Spinal fusion surgery is planned for more than one level; OR

- Congenital pseudoarthrosis; OR

- Risk of delayed or nonunion of fractures due to the following comorbidities OR for individuals undergoing a spinal fusion with the following comorbidities (list may not be all-inclusive):
  - Alcoholism
  - Chemotherapy
  - Diabetes
  - Obesity
  - Osteoporosis
  - Renal disease
  - Smoking habit
  - Steroid use

**NOTE:** These risks/comorbidities are NOT applicable to, and therefore should not be considered for, any of the diagnoses/clinical scenarios that are addressed in the Coverage Limitations section (ie, these risks/comorbidities do not override the Coverage Limitations).
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*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 BGS when the following criteria are met:

- Nonunion of long bone* fracture and **ALL** of the following:
  - Bone is noninfected; **OR**
  - Bone is stable at both ends by means of a cast or fixation; **OR**
  - The two portions of the bone involved in the nonunion are separated by less than 1 cm; **AND**
  - X-rays at least 90 days post fracture show evidence of nonhealing or nonunion; **OR**

- As an adjunct to spinal fusion surgery for individuals at high risk of pseudoarthrosis due to either of the following:
  - Previously failed spinal fusion surgery; **OR**
  - Spinal fusion surgery is planned for more than one level; **OR**

- Risk of delayed or nonunion of fractures due to the following comorbidities **OR** for individuals undergoing a spinal fusion with the following comorbidities (list may not be all inclusive):
  - Alcoholism
  - Chemotherapy
  - Diabetes
  - Obesity

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- Osteoporosis
- Renal disease
- Smoking habit
- Steroid use

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**ULTRASONIC BONE GROWTH STIMULATOR**

Humana members may be eligible under the Plan for the use of an ultrasonic BGS 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 individuals***; **OR**

- Fresh* closed fractures of the distal radius (Colles’ fracture) treated with closed reduction and cast immobilization in skeletally mature individuals***; **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 individuals***, and excluding those that are related to malignancy, when x-rays at least 90 days post fracture show evidence of nonhealing or nonunion; **OR**

- Risk of delayed or nonunion of ANY fresh* closed 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

**NOTE:** These risks/comorbidities are NOT applicable to, and therefore should not be considered for, any of the diagnoses/clinical scenarios that are addressed in the Coverage Limitations section (i.e., these risks/comorbidities do not override the Coverage Limitations).

*Fresh is considered less than or equal to seven days in duration.

**Grade I denotes that the skin opening is 1 cm 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:** The criteria for bone growth stimulators are not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to the CMS website for additional information.

**Coverage Limitations**

Humana members may **NOT** be eligible under the Plan for noninvasive or invasive electrical bone growth stimulators for any indications other than those listed above including, but not limited to, stress fractures. All other indications are considered not medically necessary as defined in the member’s individual certificate. Please refer to the member’s individual certificate for the specific definition.

Humana members may **NOT** be eligible under the Plan for the use of ultrasonic bone growth stimulators for any indications other than those listed above including, but may not be limited to, the following:

- Fractures in which the gap exceeds 1 cm; **OR**

- Fresh fractures in locations other than the distal radius, tibial diaphysis, 5th metatarsal (Jones fracture only) or scaphoid; **OR**

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- 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 (ie, use of ultrasonic BGS for fractures in the preoperative period would not be covered); OR

- Stress fractures

All other indications are considered not medically necessary as defined in the member’s individual certificate. Please refer to the member’s individual certificate for the specific definition.

Humana members may NOT be eligible under the Plan for bone growth stimulators for spondyloysis (pars interarticularis defect) or fracture due to osteoporosis. This 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**

Additional information about fractures and spinal fusions may be found from the following websites:

- American Academy of Orthopedic Surgeons
- National Library of Medicine

**Medical Alternatives**

Physician consultation is advised to make an informed decision based on an individual’s health needs.

**Provider Claims Codes**

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### CPT® Code(s)

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<tr>
<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
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### CPT® Category III Code(s)

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### HCPCS Codes

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<td>E0749 Osteogenesis stimulator, electrical, surgically implanted</td>
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Click [here](#) to view ICD-10 code(s) associated with this medical coverage policy.

### Medical Terms

**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** – Coexisting or additional diseases with reference to an initial diagnosis.

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**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.

**Delayed Union Fracture** – Healing of a fracture that takes longer than expected.

**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.

**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.

**Extremity** – Lower or upper limb, such as the leg or arm.

**Facet** – Small, smooth area on a bone or other hard surface.

**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.

**Humerus** – Bone of the upper part of the arm.
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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 – Often 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 heel to the toes.

Noninvasive – Not breaking the surface of the skin.

Nonunion Fracture – Failure of a fracture to heal.

Oblique Fracture – A fracture, the line of which runs obliquely (diagonally or slanting), neither perpendicular to nor parallel to the axis of the bone.

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 breech of the skin.
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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 (coil-like) in the bone.

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

Steroid – Type of drug used to relieve swelling and inflammation; also, the natural 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.

Ulna – One of the two bones of 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


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Part 17: bone growth stimulators as an adjunct for lumbar fusion.


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