



When Are Bone Growth Stimulators Medically Necessary?

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Overview

- Types of bone fractures and the healing process
- Ultrasound and electrical bone growth stimulators
- Indications and contraindications for bone growth stimulators
- Documentation requirements for determining medical necessity of bone growth stimulators
- Devices approved by the U.S. Food and Drug Administration (FDA) and treatment guidelines
- The role of external independent review in determining medical necessity for bone growth stimulators

Bones: Four Major Classes Based on Shape

- Long
 - Greater length than width
 - Form levers, support weight, and convey locomotion
 - Primarily found in the extremities (femur, tibia, fibula, humerus, radius, ulna, clavicle, metacarpal, metatarsal, and phalanges)
- Short
 - Designed for strength and compaction
 - Tarsal bones of the foot, carpal bones of the hand
- Flat
 - Afford protection and provide areas for muscle attachment
 - Cranial bones, sternum, ribs, and the scapulae
- Irregular
 - Vertebrae and some facial bones

Bone Fractures: Definitions

- **Fresh fracture** refers to injuries less than 2 to 4 weeks old
- **Delayed union fracture** is prolonged time to fracture union, which can result from:
 - Inadequate blood supply
 - Infection
 - Incorrect splintage
 - Intact fellow bone
- **Nonunion fracture** results from an arrest in the healing process and is defined by:
 - Motion at the fracture site
 - Radiographic evidence showing the persistence of the fracture line without bridging callus
 - Incomplete progression toward radiographic healing in the expected length of time for the given bone and further healing not expected

Bone Healing: Four Overlapping Stages

- Inflammation: occurs immediately after the fracture and lasts for a few days
 - Characterized by pain, swelling, heat and formation of a hematoma at fracture site
- Soft callus or proliferative stage: begins about 7 to 10 days after injury
 - New capillaries form; a fibrocartilaginous bridge forms across the fracture gap
- Hard callus or maturing stage: typically occurs 3 to 4 months after the injury
 - The fibrocartilaginous bridge is replaced by woven bone; results in clinical union, but the bone is still mechanically weak
- Remodeling
 - The woven bone is converted into stronger lamellar bone; the process can take months or even years, depending on the type and location of the fracture and the kind of bone involved

Ultrasound Bone Growth Stimulators

- External devices that apply low-intensity-pulsed, acoustical pressure, ultrasound waves to the skin surface above fracture sites
- Pressure waves provide micromechanical stress and strain to bone and surrounding tissue, which may cause biochemical alterations at the cellular level that enhance bone formation
- Stimulate fresh fracture healing and healing of nonunions

Electrical Bone Growth Stimulators

- Devices that use electromagnetic current to stimulate osteogenesis (bone growth)
 - Noninvasive stimulators: use inductive and conductive methods to deliver a broad, uniform, electric field, pulse electromagnetic field (PEMF), or combined electromagnetic field (CMF) to the fracture site via treatment coils or disks placed on the skin and attached to an external power supply
 - Invasive and semi-invasive stimulators: use direct current that is delivered to the fracture site (eliminates concerns regarding compliance or cooperation)
- Most studies have focused on nonunion and spinal fusion

Bone Growth Stimulators: Usage Requires Special Attention

- Broad range of FDA-approved indications
- Many variations in health plan guidelines
 - Medical necessity determination
 - Time-frame requirements
 - Documentation requirements

Determining Medical Necessity for Bone Growth Stimulators

Electrical Bone Growth Stimulators (Noninvasive, Invasive, Semi-Invasive): **Indications**

- Long bone fractures
 - Acquired secondary to trauma or surgery
 - Evidence of adequate fracture care
 - Documented confirmation that fracture is an established nonunion
- Failed fusion of a joint other than the spine
- Adjunct to spinal fusion surgery
 - Failed fusion
 - Multiple level fusion of ≥ 3 vertebrae involving ≥ 2 vertebral spaces
 - High risk of pseudoarthrosis due to previous fusion failure
 - Risk factor: obesity, smoking, diabetes, osteoporosis, continuous oral corticosteroid use >6 mos, renal disease
- Noninvasive electrical bone growth stimulator for congenital pseudoarthroses

Electrical Bone Growth Stimulators:

Contraindications

- Fracture gap >1 cm or greater than half the diameter of the bone
- Avascular or necrotic (dead) bone at the fracture site
- Pathologic long bone fractures due to malignant tumors
- Synovial pseudoarthrosis
- Osteomyelitis or infection (for invasive devices)
- Significant motion at the fracture site
- Patient not expected to comply with treatment regimen (immobilization, proper use of device)
- Postreduction displacement $>50\%$ or postreduction angulation or malalignment
- Pregnancy
- Presence of pacemaker or implantable defibrillator
- Presence of magnetic metal fixation device(s) in the area of nonunion
- Concurrent use of ultrasound stimulation

Ultrasound Bone Growth Stimulators: Indications

- Fresh fractures
 - Fresh fracture of the tibia
 - Orthopedic closed management with or without reduction
 - Fracture <7 days old
 - Skeletal maturity
- Nonunion fractures other than skull, vertebrae, or tumor-related
 - Acquired secondary to trauma or surgery
 - Evidence of adequate fracture care
 - Documented confirmation that fracture is an established nonunion

Ultrasound Bone Growth Stimulators for Fresh Fractures: **Contraindications**

- Fracture gap >1 cm or greater than half the diameter of the bone
- Fractures that are pathological or associated with malignancy
- Fractures that are unstable, or require surgical intervention or internal or external fixation
- Postreduction displacement $>50\%$ or postreduction angulation or malalignment
- Patients with implantable electrical devices (e.g., cardiac pacemakers)
- Concurrent use of electrical stimulation

Ultrasound Bone Growth Stimulators for Nonunion Fractures: **Contraindications**

- Fracture gap >1 cm or greater than half the diameter of the bone
- Avascular or necrotic (dead) bone at the fracture site
- Synovial pseudoarthrosis
- Osteomyelitis or infection
- Significant motion at the fracture site
- Patients not expected to comply with treatment regimen (immobilization, proper use of device)
- Patients with implantable electrical devices (e.g., cardiac pacemakers, implantable defibrillators)
- Patients with a magnetic metal fixation device in the area of nonunion
- Pregnancy
- Concurrent use of electrical stimulation

Bone Growth Stimulators: Many Plans Have Specific Language That Impacts Coverage

- Examples
 - Ultrasound bone growth stimulator is considered experimental, investigational, or unproven as part of the acute treatment for any fracture requiring open reduction and internal fixation
 - Electrical bone growth stimulator is considered experimental, investigational, or unproven for the treatment of fresh fractures, when used to enhance healing of fractures that are considered to be at high risk for delayed union or nonunion, for the treatment of pars interarticularis defect (i.e., spondylolysis, spondylolisthesis)
 - Bone growth stimulators are considered experimental, investigational, or unproven for toe fractures, sesamoid fractures, avulsion fractures, osteochondral lesions, displaced fractures with malalignment, synovial pseudoarthrosis, the bone gap is either >1 cm or greater than one half the diameter of the bone

Determining Medical Necessity: Requires Comprehensive Evaluation & Documentation

- Medical history
- Physical exam
- Imaging studies

Bone Growth Stimulators: **Available Devices and Treatment Guidelines**

Ultrasound Bone Growth Stimulators: FDA-Approved Device and Indications

- Exogen device
 - Colles' fracture
 - Fresh closed or open tibial diaphysis fractures
 - Nonunion

Electrical Bone Growth Stimulators: FDA-Approved Devices and Indications

- Noninvasive
 - OL 1000; SpinaLogic Bone Growth Stimulator; EBI Bone Healing System (fracture nonunion, failed fusions, congenital pseudoarthrosis of the appendicular skeletal system)
 - SpinalPak (adjunct electrical treatment to primary lumbar spinal fusion surgery for 1 or 2 levels)
 - OrthoPak (nonunion acquired secondary to trauma, excluding vertebrae and all flat bones)
- Invasive
 - OsteoGen models (fracture nonunion)
 - SpF Implantable Spine Fusion Stimulator models (fusion of 1, 2, or 3 or more levels, depending on the model)
 - Zimmer Direct Current Bone Growth Stimulator (fracture nonunions)

Bone Growth Stimulators: Treatment Guidelines

- American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)
 - Addresses use of bone growth stimulators for lumbar fusion in patients with degenerative disease of the lumbar spine
- Agency for Healthcare Research and Quality (AHRQ)
 - Evidence report on the role of bone growth stimulating devices and orthobiologics in healing of nonunion fractures

Bone Growth Stimulators: Off-Label Use

- Common due to:
 - Broad range of indications approved by the FDA
 - Varying guidelines regarding the use of the devices for different types of fractures and injuries
- Off-label use of devices
 - Legal and beneficial for some patients
 - Often little or no scientific support

Determining Medical Necessity for Bone Growth Stimulators: **The Role of Independent Review**

- An independent medical review:
 - Looks at whether or not a specific procedure was medically necessary
 - Avoids issues such as conflicts of interest, not having the appropriate specialists to review cases, or having the same physician who initially denied a claim also review an appeal
- Independent review organizations (IROs) provide specialty match
 - Especially important in orthopedic surgery due to increasing rates of off-label use of devices
 - Board-certified physician specialists who work with IROs keep up-to-date with the latest medical literature, the latest standard of care, and continually evolving therapies

Conclusions

- Bone growth stimulators have a broad range of applications
- Many health insurance policies have specific guidelines regarding the use of bone growth stimulators for different types of fractures and injuries
- Independent medical reviews
 - Provide unbiased evaluation of medical need in orthopedic surgery
 - Facilitate effective care, which is often complicated by off-label use of devices
- Independent review organizations
 - Provide ready access to specialists, which healthcare plans may lack internally
 - Allow for timely determination of whether the requested treatment falls under medical necessity guidelines and the latest standard of care

Questions and Answers

Questions & Answers

- **Are all fresh fractures of the distal radius considered necessary for use of a stimulator, or are there specific symptoms/imaging that must be seen to confirm medical necessity?**
 - No, not all fresh fractures of the distal radii need BGS. The need should be determined by the type, stability, bone condition, and position of the fracture. The more comminuted, and poor quality of the bone, the more likely the need for the BGS.
- **Is there any place for the BGS in regards to osteoporosis?**
 - Osteoporosis, the condition and not the result of disuse, is not amenable to the treatment with a BGS. It is not possible to treat all areas of the body with the BGS.

Questions & Answers

- **Would it seem necessary to require Physician Review for all use of Bone Growth Stimulators due to the complexity of determining the appropriateness of their use?**
 - Not all, since some are obvious. However, the vast majority would benefit from Physician Review. Please remember the criteria for the use of BGS includes the position of the fracture, and adequate stabilization.
- **How long should use of stimulator continue - thank you?**
 - The stimulator needs to be used until one sees the signs of true healing; i.e. bridging callus formation.

Questions & Answers

- **I am seeing bone growth stimulators requested for multi-level spinal fusions. How important is it that a person also has a risk factor?**
 - One of the criteria for the use of BGS is the multi-level spinal fusion due to the level arm placed on the segments undergoing the procedure.
- **What is your definition of a "fresh fracture"?**
 - A fresh fracture is one that is still in the phase of fibroelastic formation, and has not reached the stage of early callus formation.

Questions & Answers

- **Is there a time length definition for a delayed union fracture?**
 - That is viable by the type of fracture, and anatomical part of the body. What is normal for a scaphoid navicular fracture is delayed for a distal radius fracture.
- **For UBGs a fracture with internal or external fixation is contraindicated. What is the reason for this contraindication?**
 - Please remember the concept of “stress shielding” in bone. With fixation the electrical or ultrasound pathway would not necessarily cross the fracture the way it is intended, but rather follow the fixation device.

Questions & Answers

- **Should they be rented or purchased?**
 - Obviously in the implanted version, it must be purchased. Depending on the length of time in non invasive BGS, each company must decide when it is more feasible to purchase than rent.
- **What about BGS that are ordered pre-operatively for post-operative care?**
 - That is fine provided the fracture or surgery meets the criteria (example multi level spine fusion).

Questions & Answers

- **What about a bone growth stimulator for a two-staged spinal surgery with a risk factor of smoking? There is no indication of failed fusion because the surgery has not happened yet. The bone growth stimulator would be between surgeries.**
 - The best possible outcome would be for the patient to quit smoking at least 3 months prior to the surgery. However, if the patient is an active smoker, that would be considered a co morbidity, and be medically necessary depending on the plan language.
- **How often should patients using a noninvasive electrical stimulator see their doctor for follow-up, to assess healing progress or compliance with device usage?**
 - The patient should see the treating physician as often with the BGS as he/she would see the physician with the fracture that was undergoing normal healing.

Questions & Answers

- **Can implanted devices be left in a patient?**
 - Provided there are no complaints reference pain, or pressure points the device can be left in the patient. However, in younger patients all metallic devices should be removed. In certain cases, especially spinal fusions, the bony mass grows around the leads, and the leads cannot be completely removed without taking down a significant amount of the fusion mass.

Thank You



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