

White Paper: When Are Bone Growth Stimulators Medically Necessary?

For Health Plans, Medical Management Organizations and TPAs

Executive Summary

Although the majority of fractures heal without complications following standard non-surgical or surgical therapy, healing may be delayed or impaired in up to 10% of cases. Bone growth stimulators are devices that use either low-intensity pulsed ultrasound or electrical stimulation to induce osteogenesis, and thereby promote fracture healing. These devices are used in patients with fresh fractures and joint fusions to speed healing and to reduce the risk of delayed unions or non-unions and in patients with slow or nonhealing fractures who have not responded to other forms of fracture management.

An independent review organization (IRO) can provide ready access to specialists, which healthcare plans may lack internally, thereby allowing for the timely determination of whether the requested therapies fall under the medical necessity guidelines. Independent medical reviews facilitate the individualization and optimization of patient care by providing unbiased evaluations of the medical necessity of bone growth stimulators, which have a broad range of indications and are increasingly being sought for off-label uses.

Introduction

Bone Fractures and Healing

There are four major classes of bones: long, short, flat, and irregular. Long bones, which have greater length than width, form levels, support weight, and convey locomotion. They are primarily found in the extremities and include the femur, the tibia, the fibula, the humerus, the radius, the ulna, the clavicle, the metacarpal, the metatarsal, and the phalanges. Short bones are designed for strength, and they include the tarsal bones of the foot and the carpal bones of the hand. Flat bones afford protection and provide areas for muscle attachment. Flat bones include the cranial bones, the sternum, the ribs, and the scapulae. Irregular bones include the vertebrae and some facial bones.

Fracture healing differs from the healing of other tissues in that bone regeneration occurs instead of scar formation. Fracture healing is a complex process that consists of four overlapping stages: inflammation; the soft callus or proliferative stage; the hard callus or maturing stage; and remodeling.

The inflammatory stage occurs immediately after the fracture, lasts for a few days, and is characterized by pain, swelling, heat, and the formation of a hematoma at the fracture site. The soft callus stage begins approximately 7 to 10 days after the injury, when a fibrocartilaginous bridge forms across the fracture gap. During the hard callus state, which typically occurs 3 to 4 months after the injury, the fibrocartilaginous bridge is replaced by woven bone. Although this phase results in clinical union, the bone is still mechanically weak. During the final, remodeling phase, the woven bone is converted into stronger lamellar bone. This process can take months or even years, depending on the type and location of the fracture and the kind of bone that is involved.

Bone Growth Stimulators

Healing may be delayed or impaired in up to 10% of cases. If the healing process stops due to added risks or complications, electrical or ultrasound bone growth stimulators may be used to stimulate bone growth and enhance the healing

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process. Although bone growth stimulators have a broad range of indications that are approved by the U.S. Food and Drug Administration (FDA), many health insurance policies have specific guidelines regarding the use of these devices for different types of fractures and injuries. This has led to an increase in the off-label use of bone growth stimulators, which requires special attention in order to make medical necessity determinations and to meet time-frame and documentation requirements.

Ultrasound Bone Growth Stimulators

Ultrasound bone growth stimulation is a non-invasive intervention in which external devices apply low-intensity-pulsed, high-frequency acoustic pressure waves to accelerate the healing of fresh fractures and to promote the healing of delayed unions and non-unions that are refractory to standard treatment. Although the exact mechanism of fracture healing is unclear, it is thought that ultrasound causes biochemical changes at the cellular level that accelerate bone formation. The device is intended to be used by the patient at home, for 20 to 30 minutes per day until healing occurs.

Electrical Bone Growth Stimulators

Electrical bone growth stimulators, which can be categorized as non-invasive, invasive, or semi-invasive, use electromagnetic current to stimulate osteogenesis (bone growth). Most studies that have evaluated the use of electrical stimulation have focused on non-unions and spinal fusions.

Noninvasive bone growth stimulators use inductive and conductive methods to deliver a broad, uniform electric field, a pulse electromagnetic field (PEMF), or a combined electromagnetic field (CMF) to the fracture site via treatment coils or disks that are placed on the skin and attached to an external power supply. Invasive and semi-invasive devices use direct current that is delivered directly to the fracture site by an implanted electrode. The advantage of invasive electric bone growth systems over non-invasive systems is that a constant current is delivered to the fracture site without concerns regarding patient compliance or cooperation.

Determining Medical Necessity for Bone Growth Stimulators

Indications for use are based upon FDA labeling for specific devices and the evidence in the peer-reviewed scientific literature.

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 non-union
- ▶ 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 factors: obesity, smoking, diabetes, osteoporosis, continuous oral corticosteroid use >6 months, and renal disease
- ▶ Non-invasive electrical bone growth stimulator for congenital pseudoarthroses

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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 or proper use of device)
- ▶ Postreduction displacement >50%, angulation or malalignment
- ▶ Pregnancy
- ▶ Presence of pacemaker or implantable defibrillator
- ▶ Presence of magnetic metal fixation device(s) in the area of the non-union
- ▶ 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
- ▶ Non-union fractures other than skull, vertebrae, or tumor-related
 - Acquired secondary to trauma or surgery
 - Evidence of adequate fracture care
 - Documented confirmation that the fracture is an established non-union

Contraindications (Fresh Fractures)

- ▶ 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 external fixation
- ▶ Postreduction displacement >50%, angulation or malalignment
- ▶ Patients with implantable electrical devices (such as cardiac pacemakers)
- ▶ Concurrent use of electrical stimulation

Contraindications (Nonunion Fractures)

- ▶ 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
- ▶ Patient not expected to comply with treatment regimen (immobilization a proper use of device)
- ▶ Patients with implantable electrical devices (such as cardiac pacemakers and implantable defibrillators)
- ▶ Patients with a magnetic metal fixation device in the area of non-union
- ▶ Pregnancy
- ▶ Concurrent use of electrical stimulation

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Coverage of Bone Growth Stimulators

Many health plans have specific language that impacts the coverage of bone growth stimulators. When coverage is available, there may be certain conditions that apply. Determinations of medical necessity require comprehensive evaluations and documentation, including the patient's medical history, physical exams, and imaging studies.

Some examples of specific plan language include:

- ▶ Ultrasound bone growth stimulators are considered experimental, investigational, or unproven as part of the acute treatment for any fracture that requires open reduction internal fixation (ORIF)
- ▶ Electrical bone growth stimulators are 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 non-union, and for the treatment of pars interarticularis defects (such as 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, and bone gaps that are either >1 cm or greater than one half the diameter of the bone

Bone Growth Stimulators: Available Devices and Treatment Guidelines

There are a number of FDA-approved devices for bone growth stimulation. Please see Table 1 for a list of the devices and their respective indications.

Device	Indication(s)
Ultrasound	
Exogen device	Colles' fractures, fresh closed or open tibial diaphysis fractures, non-unions
Electrical (Noninvasive)	
OL 100 SpinaLogic Bone Growth Stimulator EBI Bone Healing System	Fracture non-unions, 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	Non-union acquired secondary to trauma, excluding vertebrae and all flat bones
Electrical (Invasive)	
OsteoGen models	Fracture non-union
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 non-unions

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The American Association of Neurological Surgeons/Congress of Neurological Surgeons Joint Section on Disorders of the Spine and Peripheral Nerves published practice guidelines for the performance of fusion procedures for degenerative disease of the lumbar spine. They support the use of electrical bone growth stimulators as adjuncts to spinal fusion. In addition, an evidence report developed by the Agency for Healthcare Research and Quality (AHRQ) defines the role of bone growth stimulating devices and orthobiologics in the healing of non-unions.

The broad range of indications approved by the FDA and the varying guidelines regarding the use of bone growth stimulators for different types of fractures and injuries may play a role in the increasing off-label use of the devices. Although the off-label use of devices is legal and may be beneficial for some patients, there is often little or no scientific evidence that supports these uses.

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

An independent medical review, which is normally used by healthcare payers, looks at whether or not a specific therapy or procedure was medically necessary. The specialty match that an independent review organization (IRO) provides is especially important in orthopedic surgery due to the rapidly evolving technologies and the increasing off-label use of devices, which requires special attention due to the varying guidelines and medical necessity requirements among health plans. The board-certified physician specialists who work with IROs keep up-to-date with the latest medical research literature and with the latest standard of care; they stay on top of continually evolving therapies as they are studied more extensively and potentially accepted into the clinical guidelines.

Conclusions

Although bone growth stimulators have a broad range of indications that are approved by the FDA, many health insurance policies have specific guidelines regarding the use of these devices for different types of fractures and injuries. This has led to many off-label uses of bone growth stimulators. By providing unbiased evaluations of the medical necessity of bone growth stimulators, external independent medical review facilitates effective patient care, which is often complicated by rapidly evolving technologies with a wide range of potential applications. Independent medical review also provides ready access to specialists, thereby allowing for timely determinations of whether the requested treatment falls under the medical necessity guidelines and the latest standard of care.

Sources

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