

Medical Affairs Policy & Procedure

Title/Service: Osteogenic Stimulator (Bone Growth Stimulator)

Revised	
Reviewed	02/25/00, 03/24/00, 01/24/03, 02/24/06, 05/18/07, 05/16/08, 12/28/09, 10/22/10, 09/16/2011
Developed	02/25/00
Policy Committee Approval	09/16/2011

Description:

Osteogenic stimulators are used to promote and augment bone growth at the site of a fracture or surgical intervention. The stimulators can be invasive (implanted) or non-invasive (topical) and can use either electrical or ultrasound energy.

Indications of Coverage:

- I. Ultrasonic osteogenic stimulators are considered medically necessary when **all** of the following conditions are met:
 - A. Nonunion of a long bone (for example, clavicle, humerus, radius, ulna, femur, tibia, fibula, phalanges, metacarpal and metatarsal bones) fracture **OR** fresh fracture (less than three weeks), nonunion, or surgical repair of one of the following:
 1. Colles' fracture (fracture of the radius at the wrist)
 2. Scaphoid (carpal navicular)
 3. Tibia
 - B. Multiple view radiologic studies performed at least three months apart document that the gap is less than one centimeter and healing has ceased for a minimum of three months despite appropriate medical care. (For purposes of review, the initial date of lack of healing progression is considered to be the latter of either the original date of fracture or the date of surgical repair for that fracture.)
- II. Electrical osteogenic stimulators are considered medically necessary when **one** of the following conditions is met:
 - A. Nonunion of a long bone (for example, clavicle, humerus, radius, ulna, femur, tibia, fibula, phalanges, metacarpal and metatarsal bones) fracture where multiple view radiologic studies performed at least three months apart document that the gap is less than one centimeter and healing has ceased for a minimum of three months despite

appropriate medical care. (For purposes of review, the initial date of lack of healing progression is considered to be the latter of either the original date of fracture or the date of surgical repair for that fracture.)

- B. Related to spinal fusion surgery where one of the following is documented:
1. Fusion failure when a minimum of nine months has elapsed since the last surgery
 2. A multiple vertebral level (three level minimum; for example, L3 - 5) procedure is performed
 3. A repeat procedure is performed to the same vertebral levels where there is a history of a failed spinal fusion
 4. Documentation of at least one of the following risk factors for fusion failure: current smoking, diabetes, renal disease
- C. Congenital or synovial pseudarthroses (a “false” joint, usually the nonunion of two bony bodies that are normally fused or a fracture that has healed with fibrous tissue, not bone)

Limitations of Coverage:

- A. Review contract and endorsements for exclusions and prior authorization or benefit requirements.
- B. If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.
- C. If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.
- D. The use of ultrasonic osteogenic stimulators for the treatment of fractures of the skull, vertebrae, or any bones with tumor invasion is considered experimental or investigative as there is insufficient peer-reviewed literature documenting the effectiveness of ultrasonic stimulators for these purposes.
- E. The use of osteogenic stimulators is considered not medically necessary for the treatment of avascular necrosis or if the fracture site or adjacent tissue is infected.

Documentation Required:

- Office notes
- Imaging reports

Rationale:

Studies have shown that up to ten percent of fractures will result in delayed unions (healing of the bone exceeds the normal healing time for a similar fracture in another individual) or a nonunion (healing of the bone has stopped and is unlikely to resume without intervention). Significant factors that play a role in bone healing include the extent of bone damage at the fracture site, the space between the bone at the fracture site, whether an infection is present, whether there is an adequate blood supply to promote healing, and the health and nutritional status of the individual. Bone growth stimulators have been shown to be effective for the treatment of some nonunion conditions of the spine and long bones when standard medical treatment has failed. Although the research is limited, the use of a bone growth stimulator for the treatment of fractures of the bones of the wrist and ankle has become common.

References:

1. Agency for Healthcare Research and Quality (AHRQ). The role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. Technology assessment program. Prepared by ECRI Evidence-based Practice Center (EPC).September 21, 2005. Available at: www.cms.hhs.gov/determinationprocess/downloads/id29TA.pdf. Accessed: 25 Aug 11.
2. American Academy of Orthopaedic Surgeons American Academy of Orthopaedic Surgeons American Academy of Orthopaedic Surgeons American Academy of Orthopedic Surgeons. Nonunions. Last reviewed and updated: September 2007. Available at: orthoinfo.aaos.org/topic.cfm?topic=A00374. Accessed: 25 Aug 11.
3. Center for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD): Osteogenic Stimulators. NCD 150.2. Baltimore, MD. Effective date: 04/27/2005. Available at: www.cms.hhs.gov/mcd/index_list.asp?list_type=ncd. Accessed: 25 Aug 11.
4. Washington State Health Care Authority. Health Technology Assessment, Bone Growth Stimulators. July 2009. Available at: www.hta.hca.wa.gov/documents/bgs_final_report_073109_updated.pdf. Accessed: 25 Aug 11.

Approved by the Medical Director