



Bone Growth Stimulation

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P&P # C.11.05

Policy

The Medical Management Department reviews referral requests for authorization of bone growth stimulation applications.

This Medical Policy does not constitute medical advice. When deciding coverage, the enrollee's specific plan document must be referenced. The terms of an enrollee's plan document (Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ from this Medical Policy. In the event of a conflict, the enrollee's specific benefit plan document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements, and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. Quartz reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

Procedure

A. Documentation Required:

In order to facilitate the authorization process, referral requests **must** include **EITHER** of the following:

1. Fresh fractures

- a. Location of fracture;
- b. Type of bone growth stimulator planned;
- c. Reason for increased risk of nonunion.

2. Nonunion of fractures

- a. Radiographic reports demonstrating nonunion or delayed union;
- b. Physical or physiological deficits related to the nonunion or delayed healing;
- c. Clinical diagnostic studies/tests/interventions to confirm the degree of impairment related to the nonunion.

B. Criteria for Medical Necessity:

Low-intensity Pulsed Ultrasound (LIPUS) Bone Stimulation is determined to be medically necessary for **ANY** of the following indications:

1. As an adjunct to treatment of **ONE** of the following fresh fractures:

- a. Closed or grade I open, tibial diaphyseal fractures not treated with intramedullary fixation; **OR**
- b. Closed fractures of the distal radius (Colles' fracture); **OR**
- c. Closed fractures of the scaphoid or 5th metatarsal bone in which there is supported risk for delayed fracture healing or nonunion due to poor blood supply due to anatomical location.

2. Treatment of a nonunion fracture or failed arthrodesis when **ALL** of the following criteria are met:

- a. Treatment is for bones other than the skull or vertebrae (e.g., radius, ulna, humerus, clavicle, tibia, femur, fibula, carpal, metacarpal, tarsal, or metatarsal); **AND**

- b. Fracture gap to be treated is ≤ 1 cm; **AND**
 - c. Nonunion is not related/secondary to malignancy; **AND**
 - d. Greater than three (3) months from the date of injury or initial treatment; **AND**
 - e. Fracture nonunion is documented by at least two sets of appropriate imaging studies separated by a minimum of ninety (90) days, confirming minimal or no visibly progressive signs of healing;
 - f. Bone is not infected; **AND**
 - g. Bone is stable on both ends by means of cast or fixation.
3. Treatment of an established stress fracture that has failed a minimum of ninety (90) days of conventional, nonsurgical management and demonstrates a fracture line that has not healed on imaging studies.

Invasive and Non-Invasive Electrical Bone Growth Stimulation is determined to be medically necessary for **ANY** of the following indications:

1. Treatment of a nonunion fracture when **ALL** of the following criteria are met:
 - a. Nonunion is located in a long bone (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, metacarpal or metatarsal bone) or the carpal and tarsal bones; **AND**
 - b. Fracture gap to be treated is ≤ 1 cm; **AND**
 - c. Fracture nonunion is documented by at least two sets of appropriate imaging studies separated by a minimum of ninety (90) days, confirming minimal or no visibly progressive signs of healing
 - d. Bone is not infected; **AND**
 - e. Bone is stable on both ends by means of cast or fixation.
2. Treatment of a failed fusion of a joint other than the spine, when a minimum of three (3) months has elapsed since the joint fusion was performed; **OR**
3. Treatment of a stress fracture that has failed a minimum of ninety (90) days of conventional, non-surgical management and demonstrates a fracture line that has not healed on imaging studies; **OR**
4. As an adjunct to spinal fusion surgery with an increased risk of fusion failure based on **ANY** of the following indications:
 - a. Prior spinal fusion at the same level (i.e., repeat spinal fusion); **OR**
 - b. Multi-level fusion procedures of 3 or more contiguous vertebrae, e.g., L3 to L5; **OR**
 - c. In the presence of significant risk factors for nonunion (e.g., smoking, renal disease, significant alcohol use, steroid use, diabetes mellitus, osteoporosis, peripheral artery disease); **OR**
 - d. Grade II spondylolisthesis with comorbidity or risk factor for nonunion; **OR**
 - e. Spondylolisthesis \geq Grade III.

C. Indications Considered Experimental, Investigational or not of Medical Necessity:

1. **Low-intensity Pulsed Ultrasound Bone Stimulation** is considered experimental, investigational or unproven for **(ANY)** the following indications (*not all-inclusive*):
 - a. A portion of the acute treatment plan (i.e., preoperative, immediately postoperative) of any fracture requiring open reduction and/or internal/external fixation;
 - b. Treatment for a fresh fracture of the clavicle, skull or spine (vertebrae);
 - c. Treatment of delayed union fractures;
 - d. Pathological fractures due to malignancy;
 - e. Avascular necrosis of femoral head;
 - f. Skeletal immaturity;

- g. In women who are pregnant or breastfeeding.
2. **Invasive and Non-invasive Electrical Bone Growth Stimulation** for nonunion of appendicular bones other than long bones is considered experimental, investigational or unproven for (**ANY**) of the following indications:
- i. Sesamoid fracture;
 - ii. Avulsion fracture;
 - iii. Osteochondral lesion;
 - iv. Displaced fractures with malalignment;
 - v. Synovial pseudoarthrosis;
 - vi. Fracture bone gap is either > 1cm or exceeds one-half the diameter of the bone;
 - vii. Pars interarticularis defect (i.e., spondylolysis, spondylolisthesis);
 - viii. Nonunion of bone which is inert and clinically appropriate for bone grafting;
 - ix. Avascular necrosis of femoral head;
 - x. Loosened hip or knee prostheses;
 - xi. Fresh fracture treatment in adults (non-invasive).

CPT/HCPCS Codes

20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Invasive (operative)
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

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