BONE GROWTH STIMULATOR

Description

Bone Growth Stimulation is the technique of promoting bone growth in difficult to heal fractures by applying a low electrical current or ultrasound to the fracture. It is done when satisfactory healing is not occurring naturally or when the pace of healing is too slow. Ultrasound and electromagnetic stimulation are used only when healing problems exist for a substantial length of time. Each method must be used for at least three (3) to six (6) months to be effective.4

Bone Growth Stimulation (invasive and non-invasive) maybe considered appropriate medical treatment under certain conditions. These conditions include traumatic fracture and non-unions of long bones (femur, tibia, fibula, humerus, radius, pelvis, or ulna) or congenital (infantile) pseudoarthroses.1 Congenital pseudoarthroses is defined as failed arthrodesis of the ankle or knee; and/or non-surgical salvage of spinal fusion surgery where at least six months have passed since the last surgery.1 Traumatic fractures must have failed to heal for three (3) months or greater for consideration.

A nonunion is established when despite adequate immobilization, non-weight bearing and conservative management, there continues to be pain and tenderness at the fracture site which are not improving, radiographic evidence taken 90 days apart reveal either no signs of healing or lack of radiological progress toward healing (e.g. persistent poor or inadequate callus formation or an unchanged and visible fracture line). Under a definition adopted by the Federal Drug Administration (FDA), a nonunion is established when at least nine (9) months have elapsed since injury and the fracture site shows no visibly progressive signs of healing for a minimum of three months.

A fresh (Acute) fracture is most commonly defined as “fresh” for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.5

Skeletal maturity occurs when a bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age and males reach skeletal maturity at around 18 years of age.5
Spinal fusion is a general term which describes the surgical results of a procedure designed to eliminate motion across a spinal segment. All fusions involve the placement of a bone graft across the spinal segment with or without a wide variety of internal fixators and techniques for post operative immobilization. There are three (3) general indications for spinal fusion: 1) to restore the integrity of the spine, to replace bone deficits, i.e. in fracture, tumor, infection; twenty 2) to maintain the correction of spinal deformity or prevent the progression of deformity, i.e. scoliosis; 3) to produce an arthrodesis to suppress painful instability. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of six (6) – nine (9) months after the original surgery, as evidenced by serial x-rays over a course of four (4) months.  

THC considers requests for Bone Stimulation on a case-by-case basis when supporting documentation demonstrates medical necessity and clinical decision criteria is met. THC utilizes criteria derived from evidenced based medicine and nationally accepted Standards of Care from recognized sources such as Centers for Medicare and Medicaid, Blue Cross Blue Shield, and well established managed care organizations.

Additional factors taken into consideration during the clinical review process include (not all inclusive):  

- Age  
- Pertinent past and current medical history  
- Current treatment and progress  
- Individual need  
- Local Delivery System  
- Psychological factors/home environment (if/when applicable)  

### Decision Criteria

#### Administrative  
1. Referral from Primary Care Physician is required along with appropriate supporting medical documentation  
2. Services must be performed by a Total Health Care affiliated or contracted physician, hospital, or other provider  
3. Prior authorization is required by Plan’s Medical Director  
4. Affected member must have current eligibility at time of request
Clinical

**Electric Bone Growth Stimulator Decision Criteria**

**Long Bones:**
1. The fracture was acquired secondary to trauma or surgery; and
2. At least four (4) months have passed since the date of fracture; and
3. There is evidence of adequate fracture care; and
4. Documented confirmation that the fracture is an established non-union:
   a. The non-union is confirmed by serial radiographs (bone x-rays) over the last three (3) months obtained prior to starting treatment with the stimulator, which show no sign of continued healing; and
   b. The non-union fracture is confirmed in the medical record by radiographic evidence that fracture healing has ceased for three (3) or more months prior to starting treatment with the stimulator.5
5. The fracture gap is one centimeter or less1
6. Patient can be adequately immobilized and is of an age likely to comply with non-weight bearing1

**Infantile (congenital) pseudoarthroses1:**
1. Failed joint fusion because of failed arthrodesis of the ankle or knee
2. Pseudoarthrosis of the spine as a non-surgical salvage. At least six (6) months must have passed since the last spinal fusion surgery

**Spinal Fusion Surgery:**
1. Electric Bone Growth Stimulation may also be indicated as an adjunct to high-risk lumbar and/or lumbosacral spinal fusion cases that meet one or more of the following criteria:1
   a. Prior fusion failure(s) where a minimum of 6 months has elapsed since the last surgery; or
   b. Multi-level fusions of three (3) or more vertebrae involving two (2) or more vertebral spaces (e.g., L3-5, L4-S1, etc.), or
   c. Grade III or worse spondylolisthesis
   d. High risk of Pseudoarthrosis due to previous fusion failure,
   **AND**
2. Has one of the following risk factors:
   a. Obesity
   b. Smoker
   c. Diabetes
   d. Osteoporosis
   e. Continuous oral corticosteroid use for greater than six (6) months
   f. Renal Disease
Exclusions

1. Electrical Bone Growth Stimulation for treatment of fractures less than six (6) months old, or fractures of short bones such as scaphoid bone of the wrist or for epiphyses
2. Electrical Bone Growth Stimulation as adjunct to cervical fusion surgery and for failed cervical spinal fusion
3. Patients with active osteomyelitis
4. Patients with fractures due to cancer
5. Patients who are pregnant or nursing
6. Patients who are using drugs which alter bone metabolism
7. Head, cervical, or skull fractures
8. Patients with elective pacemakers must be evaluated and given medical clearance by cardiologist before using device

Ultrasonic Bone Growth Stimulator Decision Criteria

Fresh Fractures:

1. For ultrasound stimulation treatment of a fresh fracture, all of the following must be met:
   a. Fresh fracture of the tibia; and
   b. Orthopedic closed management with or without reduction; and
   c. Fracture is less than seven days old; and
   d. Skeletal maturity evidenced.

Exclusions for ultrasound fresh fractures

1. Fracture gap greater than one centimeter
2. Fractures that are pathological or associated with malignancy
3. Fractures that are unstable, or require surgical intervention or internal or external fixation
4. Postreduction displacement greater than 50 percent or postreduction angulation or malalignment
5. Patients with elective pacemakers must be evaluated and given medical clearance by cardiologist before using device
6. Concurrent use of electrical stimulation
2. For ultrasound stimulation treatment of a non-union fracture other than of the skull, vertebrae, or that is tumor related, all of the following criteria must be met:
   a. The fracture was acquired secondary to trauma or surgery; and
   b. At least four (4) months have passed since the date of fracture; and
   c. There is evidence of adequate fracture care; and
   d. Documented confirmation that the fracture is an established non-union:
      i. The non-union is confirmed by serial radiographs (bone x-rays) over the last three (3) months obtained prior to starting treatment with the stimulator, which show no sign of continued healing; and
      ii. The non-union fracture is confirmed in the medical record by radiographic evidence that fracture healing has ceased for three (3) or more months prior to starting treatment with the stimulator.
   e. The fracture gap is one centimeter or less
   f. Patient can be adequately immobilized and is of an age likely to comply with non-weight bearing

**Exclusions for ultrasound non-union fractures**

1. Ultrasound Bone Growth Stimulation for treatment of fractures less than six (6) months old, or fractures of short bones such as scaphoid bone of the wrist or for epiphyses
2. Patients with active osteomyelitis
3. Patients with fractures due to cancer
4. Patients who are pregnant or nursing
5. Patients who are using drugs which alter bone metabolism
6. Head, cervical, or skull fractures
7. Patients with elective pacemakers must be evaluated and given medical clearance by cardiologist before using device
8. Concurrent use of electrical stimulation

**Bibliography**

1. Centers for Medicare and Medicaid Services, Blue Cross Blue Shield of Massachusetts, Policy 157, Posted 12/09/05, Fracture Healing Devices (Electric Bone Growth Stimulation and Ultrasound-Accelerated
2 Standards and Guidelines for the Accreditation of MCO’s, 2006, NCQA, National Committee for Quality Assurance, 2000 L Street, NW, Suite 500, Washington, DC, 20036

3 Aetna Clinical Policy Bulletin: Bone Growth Stimulators Number: 0343

4 thefreedictionary.com

5 Bone Growth Stimulators Medica Policy No. III-DEV.07