

# MEDICA®

## UTILIZATION MANAGEMENT POLICY

**TITLE:** BONE GROWTH STIMULATORS

**EFFECTIVE DATE:** July 1, 2015

**DOCUMENT HISTORY**

Original Endorsement Date: May, 1991

Subsequent Endorsement Date(s): 02/1992, 03/1994, 03/1995, 07/1996, 09/1997, 12/1998 (Not Approved), 09/1999 (Approved), 09/2000, 10/2001, 09/2002, 09/2003, 01/2004, 02/2005, 04/2006, 04/2007, 04/2008, 04/2009, 04/2010, 04/2011, 04/2012, 04/2013, 04/2014, 04/2015

*This policy was developed with input from specialists in orthopedics, orthopedic surgery, and neurosurgery and endorsed by the Medical Policy Committee.*

**IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**

*These services may or may not be covered by all Medica plans. Please refer to the member's plan document for specific coverage information. If there is a difference between this general information and the member's plan document, the member's plan document will be used to determine coverage.*

*With respect to Medicare, Medicaid and MinnesotaCare members, this policy will apply unless these programs require different coverage.*

*Medica may use tools developed by third parties, such as MCG Care Guidelines®, to assist in administering health benefits. Medica's use of MCG Care Guidelines is limited to specific Medica individual and family business (IFB) members who are identifiable with group number "IFB." MCG Care Guidelines that apply to this policy are ACG: A-0414 (AC), Bone Growth Stimulators, Ultrasonic; and ACG: A-0565 (AC), Bone Growth Stimulators, Electrical and Electromagnetic.*

*Medica utilization management (UM) policies and MCG Care Guidelines are not intended to be used without the independent clinical judgment of a qualified health care provider taking into account the individual circumstances of each member's case. Medica UM policies and MCG Care Guidelines do not constitute the practice of medicine or medical advice. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice.*

*Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica UM policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.*

**PURPOSE**

To promote consistency between reviewers in utilization management decision-making by providing the criteria that generally determines the medical necessity of bone growth stimulators. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

**BACKGROUND**

I. Definitions

- A. **Delayed union** is when the healing process continues, but the fracture takes longer than usual to heal. The fact that a bone is delayed in its union does not mean that it will become a non-union. Reasons for delayed union may include inadequate reduction, inadequate immobilization, and impaired blood supply.
- B. **Electrical bone growth stimulators** use electromagnetic current to stimulate osteogenesis (bone growth).

- C. **Non-union fracture** is the result of an arrest in the healing process and is defined by the following three findings:
1. Motion at the fracture site,
  2. Radiographic evidence showing the persistence of the fracture line without bridging callus,
  3. Incomplete progression toward radiographic healing in the expected length of time for the given bone and further healing not expected.
- D. **Long bones** are bones that consist of a cylindrical shaft (body) with a central cavity and two extremities, which are usually expanded for purposes of articulation and muscular attachment. Long bones are the femur, tibia, fibula, humerus, radius, ulna, clavicle, metacarpal, metatarsal, and phalanges.
- E. **Skeletal maturity** occurs when bone growth ceases after puberty and refers to demonstration of fusion of skeletal bones. Females reach skeletal maturity at approximately 16 years of age, while males reach skeletal maturity around 18 years of age. Radiographs of either the knee or of the hand and wrist with subsequent mathematical calculations are often used when exact measurement of skeletal maturity is warranted.
- F. **Ultrasound bone growth stimulators** are external devices that apply low-intensity, pulsed, acoustical pressure, ultrasound waves to the skin surface above fracture sites. Although the exact mechanism of action is unclear, it is known that pressure waves provide micromechanical stress and strain to bone and surrounding tissue. It is speculated that this stress and strain leads to biochemical alterations at the cellular level that leads to enhanced bone formation.
- G. **Multiple level spinal fusion** involves fusion of three or more vertebrae (e.g., L3-L5, L4-S1).

II. Comments

- A. The most common symptoms of non-union fracture are pain and motion at the fracture site.
- B. Electrical bone growth stimulators fall into one of three categories: invasive, semi-invasive or non-invasive.
1. Invasive and semi-invasive devices use direct current that is delivered internally to the fracture site via implanted electrodes.
  2. Non-invasive devices use an external power supply to create pulsed electromagnetic fields (PEMF), combined magnetic fields (CMF), or direct current. Leads are placed over the cast and the electromagnetic field is established between the leads and fracture site.
- C. Ultrasound bone growth stimulation has not been adequately tested in children; in pregnant or nursing women; in individuals with sensory paralysis, vascular insufficiency, thrombophlebitis, abnormal skin sensitivity, nutritional deficiency, or alcoholism; or with patients receiving medications known to affect bone metabolism.
- D. A 2001 specialty panel of local orthopedic surgeons indicated that generally there is no medically appropriate use for ultrasound bone growth stimulators for fresh radial fractures. However, for a very small population of fresh tibial fractures, the panel felt it may be useful.

MEDICAL NECESSITY CRITERIA

**Electrical bone growth stimulators**

- I. Electrical bone growth stimulator(non-invasive, semi-invasive or invasive) is considered medically necessary when documentation in the medical records indicates that **one of the following** are met:
- A. **Long bone fracture**  
**All of the following** criteria must be met:
1. The fracture was acquired secondary to trauma or surgery
  2. There is evidence of adequate fracture care (e.g., casting, immobilization, internal fixation)
  3. The fracture gap is less than or equal to 1 centimeter
  4. Documented confirmation that the fracture is an **established non-union** as indicated by **all of the following**:
    - a. The non-union fracture is defined in the medical record by radiographic evidence that fracture healing has ceased for three or more months *prior* to starting treatment with the osteogenesis stimulator
    - b. The non-union fracture is documented in the medical record by interpretation of a minimum of two sets of radiographs obtained *prior* to starting treatment with the osteogenic stimulator, with radiographic sets separated by a minimum of 90 days (measured from the date of the most recent medical or surgical intervention).
- B. **Lumbar spinal fusion**  
**One of the following** must be met:
1. **Failed lumbar fusion** when a minimum of six months has elapsed since the last surgery.

2. **Adjunctive use with lumbar fusion surgery** on a mature skeleton when **all of the following** criteria is met:

a. **One of the following** is met:

- 1) Previously failed lumbar fusion, when a minimum of six months has elapsed since the last surgery
- 2) Multiple level lumbar fusion of three or more vertebrae involving two or more vertebral spaces (e.g., L3-L5, L4-S1, etc.)
- 3) High risk of pseudoarthrosis due to previous lumbar fusion failure

b. The member has **one of the following** risk factors:

- 1) Obesity (BMI equal to or greater than 30)
- 2) Smoker
- 3) Diabetes
- 4) Osteoporosis
- 5) Continuous oral corticosteroid use for greater than six months
- 6) Renal Disease

C. **Congenital pseudoarthroses** using only non-invasive electrical bone growth stimulator.

II. No documented contraindications present as indicated by **all of the following**:

- A. No avascular or necrotic (dead) bone at the fracture site
- B. No pathologic long bone fractures due to malignant tumors
- C. No synovial pseudoarthrosis
- D. No osteomyelitis or infection (for invasive devices)
- E. No significant motion at the fracture site
- F. No inability to comply with treatment regimen (immobilization, proper use of device)
- G. No postreduction displacement greater than 50 percent or postreduction angulation or malalignment
- H. Not currently pregnant
- I. No presence of pacemaker or implantable defibrillator
- J. No presence of magnetic metal fixation device(s) in the area of non-union
- K. No concurrent use of ultrasound stimulation.

### Ultrasound bone growth stimulators

I. Ultrasound bone growth stimulator is considered medically necessary when documentation in the medical records indicates that **one of the following** are met:

A. **Fresh fracture**

**All of the following** criteria must be met:

1. Fresh fracture of the tibia
2. Orthopedic closed management with or without reduction
3. Fracture less than seven days old
4. The fracture gap is less than or equal to 1 centimeter
5. Skeletal maturity evidenced
6. No documented contraindications present as indicated by **all of the following**:
  - a. No fracture that is pathological or associated with malignancy
  - b. No fracture that is unstable, or requires surgical intervention or internal or external fixation
  - c. No postreduction displacement greater than 50 percent or postreduction angulation or malalignment
  - d. No presense of pacemaker or implantable defibrillator
  - e. No concurrent use of electrical stimulation.

B. **Non-union fracture** other than of the skull, vertebrae, or that is tumor-related

**All of the following** criteria must be met:

1. The fracture was acquired secondary to trauma or surgery
2. There is evidence of adequate fracture care (e.g., casting, immobilization, internal fixation)
3. The fracture gap is less than or equal to 1 centimeter
4. Documented confirmation that the fracture is an **established non-union** as indicated by **all of the following**:
  - a. The non-union fracture is defined in the medical record by radiographic evidence that fracture healing has ceased for three or more months *prior* to starting treatment with the osteogenesis stimulator
  - b. The non-union fracture is documented in the medical record by interpretation of a minimum of two sets of radiographs obtained *prior* to starting treatment with the osteogenic stimulator, with radiographic sets separated by a minimum of 90 days (measured from the date of the most recent

- medical or surgical intervention).
5. No documented contraindications present as indicated by **all of the following**:
    - a. No avascular or necrotic (dead) bone at the fracture site
    - b. No synovial pseudoarthrosis
    - c. No osteomyelitis or infection
    - d. No significant motion at the fracture site
    - e. No inability to comply with treatment regimen (immobilization, proper use of device)
    - f. No presence of pacemaker or implantable defibrillator
    - g. No presence of magnetic metal fixation device(s) in the area of non-union
    - h. Not currently pregnant
    - i. No concurrent use of electrical stimulation.

NOTE: Ultrasound bone growth stimulation for the treatment of **fresh fracture of the radius** is **not medically necessary**.

#### COVERAGE ISSUES

1. Prior authorization **is required** for bone growth stimulation. Coverage is limited to devices that have FDA approval for use on the involved bone.
2. Coverage may vary according to the terms of the member's plan document.
3. For Medicare members, refer to the following, as applicable:
  - Centers for Medicare and Medicaid (CMS). National Coverage Determination for *Osteogenic Stimulators* (150.2). Available at: <http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=65&ncdver=2&SearchType=Advanced&CoverageSelection=National&NCSelection=NC D%7cMCD&Keyword=Osteogenic+Stimulators&KeywordLookUp=Title&KeywordSearchType=Exact&kq=tru&bc=IAAAACAAAA&>. Accessed February 24, 2015.
4. Concurrent use of electrical and ultrasound stimulation devices is not eligible for coverage.
5. Electrical bone growth stimulation *is investigative and therefore not covered* for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to: (1) long bone, fresh fractures; (2) nonunion of appendicular bones other than long bones; (3) delayed union of long bone fractures, (4) biologically inert nonunions better suited to bone grafting, and (5) cervical spinal fusion surgery (failed fusion and adjunct use with surgery).
6. Ultrasound bone growth stimulation *is investigative and therefore not covered* for all indications not specifically mentioned in the Medical Necessity Criteria section, including but not limited to: (1) delayed union fractures; (2) non-union fractures of the skull, vertebrae, and those that are tumor-related; and (3) fresh non-tibial fractures.
7. Interferential current stimulation *is investigative and therefore not covered*. Please see Medica Coverage Policy, *Interferential Current Stimulation*.
8. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's plan document.
9. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Medica administrative handbook.

#### References:

1. Akai M, Hayashi K. Effect of electrical stimulation on musculoskeletal systems; a meta-analysis of controlled clinical trials. *Bioelectromagnetics*. 2002;23:132-143.
2. Aaron RK, Ciombor D McK, Simon BJ. Treatment of nonunions with electric and electromagnetic fields. *Clin J Orthop Rel Res*. 2004;419:21-29.
3. Busse JW, Bhandari M, Kulkarni AV, Tunks E. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. *Can Med Assoc J*. 2002;166(4):437-441.
4. Dimitriou R, Babis GC. Biomaterial osseointegration enhancement with biophysical stimulation. *J Musculoskeletal Neuronal Interact*. 2007;7(3):253-265.
5. Divelbiss BJ, Adams BD. Electrical and ultrasound stimulation for scaphoid fractures. *Hand Clinics*. 2001;17(2):697-701.
6. ECRI Institute. *Emerging Technology Evidence Report: Electrical Bone Growth Stimulation (Cervical-Stim) for Facilitating Healing after Cervical Fusion*. July 2013. Plymouth Meeting, PA.
7. ECRI Institute. *Hotline Response: Electric Bone Growth Stimulators for Treating Acute and Nonunion Bone Fractures*. September 2014. Plymouth Meeting, PA.

8. Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed electromagnetic field stimulation for cervical fusion. *Spine Jour.* 2008;8:436-442.
9. Gan JC, Glazer PA. Electrical stimulation therapies for spinal fusions: current concepts. *Eur Spine Jour.* 2006;15:1301-1311.
10. Griffin XL, Parsons N, Costa ML, Metcalfe D. Ultrasound and shockwave therapy for acute fractures in adults. *Cochrane Database Syst Rev.* 2014;(6): CD008579. doi: 10.1002/14651858.CD008579.pub3.
11. Hayes, Inc. *Hayes Directory Report: Electrical Bone Growth Stimulation, Noninvasive.* September 2009. Annual Review last updated August 2013. [Archived October 2014]. Lansdale PA.
12. Hayes, Inc. *Hayes Directory Report: Ultrasound Bone Growth Stimulation.* September 2009. Annual Review last updated August 2013. [Archived October 2014]. Lansdale PA.
13. Hayes, Inc. *Hayes Directory Report: Electrical Bone Growth Stimulation, Invasive.* September 2009. Annual Review last updated August 2013. [Archived October 2014]. Lansdale PA.
14. Hodges SC, Eck JC, Humphreys C. Use of electrical bone stimulation in spinal fusion. *J Am Acad of Orthop Surg.* 2003;11(2):81-88.
15. Khan U, Laurencin CT. Fracture repair with ultrasound: clinical and cell-based evaluation. *J Bone Joint Surg Am.* 2008;90(Suppl 1):138-144.
16. Mollon B, da Silva V, Busse JW, et al. Electrical stimulation for long-bone fracture-healing: a meta-analysis of randomized controlled trials. *Jour Bone Joint Surg.* 2008;90:2322-2330.
17. National Heart, Lung, and Blood Institute. *Body Mass Index Table*  
1. [http://www.nhlbi.nih.gov/health/educational/lose\\_wt/BMI/bmi\\_tbl.htm](http://www.nhlbi.nih.gov/health/educational/lose_wt/BMI/bmi_tbl.htm). Accessed February 24, 2015.
18. Nolte PA, van der Krans A, Patka P, Janssen, Ryaby JP, Albers GHR. Low-intensity pulsed ultrasound in the treatment of nonunion. *J Trauma.* 2001;51(4):693-703.
19. Phieffer LS, Goulet JA. Delayed unions of the tibia. *J Bone Joint Surg.* 2006;88-A(1):206-216.
20. Resnick DK, Choudhri TF, Dailey AT, et al. Guideline for the performance of fusion procedures for degenerative disease of the lumbar spine. Part 17: bone growth stimulators and lumbar fusion. *J Neurosurg: Spine.* 2005;2(6):737-740.
21. Ricardo M. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. *Int Orthop.* 2006;30(2):123-127.
22. Saxena A, DiDomenica LA, Wedtfeldt A, et al. Implantable electrical bone stimulation for arthodeses of the foot and ankle in high-risk patients: a multicenter study. *J Foot Ankle Surg.* 2005;44(6):450-454.
23. Walker NA, Denegar CR, Preische J. Low-intensity pulsed ultrasound and pulsed electromagnetic field in the treatment of tibial fractures: a systematic review. *J Athlet Train.* 2007;42(4):530-535.
24. Zura RD, Sasser B, Sabesan V, et al. A survey of orthopaedic traumatologists concerning the use of bone growth stimulators. *J Surg Orthop Adv.* 2007;16(1):1-4.