



**Subject:** *Bone Growth Stimulators – Electric & Ultrasound*

**Number:** *200311-0002*

Effective date: 11/17/2003

Revision date(s): 11/2000, 01/2001, 11/05/2003, 01/21/2004

**Important note**

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website:

<http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

**Overview**

An **electrical bone growth stimulator (EBGS)** is a *durable medical equipment (DME)* device used to treat fractures with established nonunion; meaning, fractures with both clinical and radiological evidence of no progressive signs of healing.

There are three types of electrical bone growth stimulators: invasive, semi-invasive and noninvasive. Invasive and semi-invasive devices utilize direct current delivered internally via implanted electrodes. Noninvasive devices may use direct current or pulsed electromagnetic fields. The current is delivered to the appropriate site via externally mounted cathodes for direct current or coils for electromagnetic fields.

**Ultrasound bone growth stimulators** are external DME devices that apply low-intensity, pulsed ultrasound to the skin surface above fracture sites. While the exact mechanism of ultrasound stimulation of bone healing is unknown, the theory is that the pressure waves it produces provides micro-mechanical stress and strain causing biochemical alterations at the cellular level, which leads to enhanced bone formation.

Ultrasound bone growth stimulators are also referred to as Ultrasonic Accelerated Fracture or Sonic Accelerated Fracture Healing System (SAFHS). It consists of two main components: a signal generator and a small transducer connected by a cable to the generator. The transducer is applied to the skin over the fracture site.

**Policy and criteria**

**NOTE:** These services require prior authorization by the Plan Medical Director.

**When services are covered:**

We cover **Electrical Bone Growth Stimulators (EBGS)** for **commercial plan members** when the following *Indications* and *Criteria* are met.

EBGS Indications:	Criteria:
<ul style="list-style-type: none"> <li>• <b>Noninvasive</b> <ul style="list-style-type: none"> <li>○ Nonunion of long bone fractures; OR</li> <li>○ Failed fusion, where a minimum of 9 months has elapsed since the last surgery; OR</li> <li>○ Congenital pseudoarthroses; OR</li> <li>○ As an adjunct to spinal fusion surgery for patients at high risk for fusion failure or pseudoarthroses</li> <li>○ Fresh, closed posteriorly displaced distal radius (Colles) fracture; OR</li> <li>○ Acute closed or Grade I open tibial fractures after closed reduction or surgery and immobilization.</li> </ul> </li> <li>• <b>Invasive</b> <ul style="list-style-type: none"> <li>○ Nonunion of long bone fractures; OR</li> <li>○ As an adjunct to spinal fusion surgery for patients at high risk for fusion failure or pseudoarthroses.</li> </ul> </li> </ul> <p><b>Note:</b> Long bones include but are not limited to the humerus, femur, radius, ulna, tibia, fibula, clavicle; fifth metatarsal (when significant pain is present; carpal and/or tarsal bones.</p>	<ul style="list-style-type: none"> <li>• Patient must be 20 years of age or older OR demonstrate proof of skeletal maturity: AND</li> <li>• The fracture gap is <math>\leq 1</math> centimeter; AND</li> <li>• For <b>nonunion of long bone fractures</b>, serial radiographs have confirmed that fracture healing has ceased for <b>3 or more months</b> prior to starting treatment with the BGS, as demonstrated by: <ul style="list-style-type: none"> <li>○ A minimum of 2 sets of radiographs, each including multiple views of the fracture site AND</li> <li>○ Separated by a minimum of 90 days</li> </ul> </li> <li>• <b>High risk of spinal fusion failure</b> exists when: <ul style="list-style-type: none"> <li>○ Previously failed spinal fusion at the same site, OR</li> <li>○ Grade II or worse spondylolisthesis, OR</li> <li>○ Undergoing a multiple level fusion (involving 3 or more vertebrae: e.g., L3-L5, L4-S1, etc.), OR</li> <li>○ Body mass index (BMI) of <math>\geq 35</math>, OR</li> <li>○ Degenerative osteoarthritis, OR</li> <li>○ Current alcohol or tobacco use, OR</li> <li>○ Previous disc surgery, OR</li> <li>○ Diabetes or renal disease</li> </ul> </li> </ul>

We cover EBGS for Medicare plan members when the following *Indications* and *Criteria* are met.

EBGS Indications:	Criteria:
<ul style="list-style-type: none"> <li>• <b>Noninvasive</b> <ul style="list-style-type: none"> <li>○ Nonunion of long bone fractures; OR</li> <li>○ Failed fusion, where a minimum of 9 months has elapsed since the last surgery; OR</li> <li>○ Congenital pseudoarthroses; OR</li> <li>○ As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g.,</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• For <b>nonunion of long bone fractures</b>, serial radiographs have confirmed that fracture healing has ceased for <b>3 or more months</b> prior to starting treatment with the BGS, as demonstrated by: <ul style="list-style-type: none"> <li>○ A minimum of 2 sets of radiographs, each including multiple views of the fracture site; AND</li> <li>○ Separated by a minimum of 90 days</li> </ul> </li> </ul>

<p>L3-L5, L4-S1, etc).</p> <ul style="list-style-type: none"> <li>• <b>Invasive</b> <ul style="list-style-type: none"> <li>○ Nonunion of long bone fractures; OR</li> <li>○ As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (e.g., L3-L5, L4-S1, etc).</li> </ul> </li> </ul> <p><b>Note:</b> Long bones include but are not limited to the humerus, femur, radius, ulna, tibia, fibula, or clavicle.</p>	
---	--

We cover **Ultrasound Bone Growth Stimulators (U/S BGS)** for **commercial plan members** when the following *Indications* and *Criteria* are met.

<b>U/S BGS Indications:</b>	<b>Criteria:</b>
<ul style="list-style-type: none"> <li>• Fresh, closed or Grade I open tibial diaphyseal fractures after closed reduction and cast immobilization</li> <li>• Fresh, closed fracture of distal radius (Colles fracture) after closed reduction and cast immobilization</li> <li>• Treatment of nonunion fractures, excluding the skull or vertebra, or fractures related to malignancy</li> </ul> <p><b>Note:</b> The nonunion fractures should not be older than 5 years, as U/S BGS is not as efficacious for longstanding fractures.</p>	<ul style="list-style-type: none"> <li>• Patient must be 20 years of age or older OR demonstrate proof of skeletal maturity: AND</li> <li>• The fracture gap is <math>\leq 1</math> centimeter; AND</li> <li>• For <b>nonunion fractures</b>, serial radiographs have confirmed that fracture healing has ceased for <b>3 or more months</b> prior to starting treatment with the BGS, as demonstrated by: <ul style="list-style-type: none"> <li>○ A minimum of 2 sets of radiographs, each including multiple views of the fracture site AND</li> <li>○ Separated by a minimum of 90 days</li> </ul> <p style="text-align: center;">AND</p> </li> <li>• Indications that the patient failed at least 1 surgical or medical intervention for the treatment of the fracture</li> </ul>

We cover **U/S BGS** for **Medicare plan members** when the following *Indications* and *Criteria* are met.

<b>U/S BGS Indications:</b>	<b>Criteria:</b>
<ul style="list-style-type: none"> <li>• Treatment of nonunion fractures</li> </ul>	<ul style="list-style-type: none"> <li>• For <b>nonunion fractures</b>, serial radiographs have confirmed that fracture healing has ceased for <b>3 or more months</b> prior to starting treatment with the BGS, as demonstrated by: <ul style="list-style-type: none"> <li>○ A minimum of 2 sets of radiographs, each including multiple views of the fracture site AND</li> <li>○ Separated by a minimum of 90 days</li> </ul> </li> </ul>

	<p>AND</p> <ul style="list-style-type: none"> <li>• Indications that the patient failed at least 1 surgical intervention for the treatment of the fracture</li> </ul>
--	---

**Important note:** The Medicare national non-coverage policy related to U/S BGS for fresh fractures and delayed unions remains in place. This policy relates only to non-union as defined above.

**When services are not covered:**

We do not cover EBGS or U/S BGS devices when the above criteria are not met.

We do not cover EBGS or U/S BGS devices when the ANY of the following CONTRAINDICATIONS exist:

- Fracture of the skull, vertebra or due to cancer
- Fracture of short bones or epiphyses
- Fractures that need additional reduction or are comminuted
- Fractures with post-reduction displacement of > 50%
- Fractures with internal or external fixation
- Fracture gaps > 1 centimeter
- Infantile non-union or failed joint fusion resulting from failed arthrodesis of the ankle or knee
- Avascularity, vascular insufficiency or other vascular problems (i.e., thrombophlebitis) or severe osteoporosis
- Medications that may interfere with or alter bone metabolism and healing
- Osteomyelitis, active infections or necrotic bone
- Patients with cardiac pacemakers should consult their cardiologist before using either device
- Patients who are pregnant or nursing
- Patients with cancer, spondylitis, Paget’s disease, renal disease, or diabetes
- Sensory paralysis
- Synovial pseudoarthritis

**Note:** The U/S BGS cannot be used concurrently with an EBGS devices.

**Codes:**

Codes	Number	Description
CPT	20974	Electrical stimulation to aid bone healing; non-invasive (non- operative)
	20975	Electrical stimulation to aid bone healing; invasive (operative)
	20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive, nonoperative
HCPCS	E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal applications
	E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
	E0749	Osteogenesis stimulator, electrical, surgically implanted
	E0760	Osteogenic stimulator, low intensity ultrasound, non-invasive

Copyright © 2004 American Medical Association, Chicago, IL

**FCHP Products to which this policy applies:**

- ⊕ Direct & Select Care (HMO)
- ⊕ Flex Care Direct & Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ Fallon MassHealth
- ⊕ Non-Group: Independent Care, Direct enrollment, & Bill at home
- ⊕ Medicare Plan – *reminder* to refer to current CMS for policy and criteria

**References**

1. Abeed RI, Naseer M, Abel EW. Capacitively coupled electrical stimulation treatment: results from patients with failed long bone fracture unions. *J Orthop Trauma* 1998 Sept-Oct;12(7):510-3.
2. Brighton CT, et al., *Tibial nonunion treated with direct current, capacitative coupling, or bone graft*. *Clin Ortho* 1995 Dec;(321):223-34
3. Busse JW, et al. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. *CMAJ JAMC* 2002 Feb 19;166(4):437-41.
4. Centers for Medicare & Medicaid Services. National Coverage Determinations. Osteogenic Stimulation. Publication Number 6, Transmittal Number 131. January 2001.
5. Centers for Medicare and Medicaid Services. National Coverage Policy Revision. Electrical stimulation for fracture healing (CAG-00022). Decision Memorandum. July 2000.
6. Cook SD, Ryaby JP, McCabe J, et al. Acceleration of tibia and distal radius fracture healing in patients who smoke. *Clin Orthop*. 1997;337:198-207.
7. Eck JC, Hodges SD, Humphries SC. Techniques for stimulating spinal fusion: efficacy of electricity, ultrasound and biological factors in achieving fusion. *Am J Ortho* 2001 Jul;30(7):535-41.
8. Emami A, Petren-Mallmin M, Larsson S. No effect of low-intensity ultrasound on healing time of intramedullary fixed tibial fractures. *J Orthop Trauma* 1999;13(4):252-7.
9. Exogen. Summary of safety and efficacy data. Exogen 2000 or Sonic Accelerated Fracture Healing System. PMA Number:900009, Suppl. 6. Piscataway, NJ: Exogen, 2000.
10. Farley, D. New ways to heal broken bones. *FDA Consumer Magazine*. April 1996.
11. Frankel VH, et al. Results of prescription use of pulse ultrasound therapy in fracture management. *Surg Technol Internat VII* 1998:389-93.
12. Hadjuargyrou, M, McLeod, K, Ryaby, JP, Rubin, C. Enhancement of fracture healing by low intensity ultrasound. *Clin Orthopedics and Related Research*. 1998; 355S:S216-S229.
13. Hayes, Winifred S. Electrical bone growth stimulation, invasive. April 2001. Updated October 2003.
14. Hayes, Winifred S. Electrical bone growth stimulation, non-invasive. August 2001. Updated October 2003.
15. Hayes, Winifred S. Ultrasound bone growth stimulation for fracture healing. November 2000. Updated November 2002.
16. Heckman JD, Ryaby JP, McCabe J, et al. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. *J Bone Joint Surg Am*. 1994;76(1):26-34.
17. Kristiansen TK, Ryaby JP, McCabe J, et al. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled study. *J Bone Joint Surg Am*. 1997;79 (7):961-973.
18. Mayr E, Frankel V, Rüter A. Ultrasound - an alternative healing method for non-unions? *Arch Orthop Trauma Surg* 2000 Spring;120:1-8.
19. Mayr E, Wagner S, Ecker M, et al. Ultrasound therapy for nonunions (pseudarthrosis): 3 case reports. *Unfallchirurg*. 1999;123:191-196.
20. Mayr E, Wagner S, Rüter A. Treatment of nonunions by means of low-intensity ultrasound. *Unfallchirurg*. 1997;121:958-962.
21. Nolte PA, et al. Low-intensity pulsed ultrasound in the treatment of nonunions. *J Trauma Injur Infect Crit Care* 2001 Oct;51:693-703.
22. Oishi M and Onesti ST. Electrical bone graft stimulation for spinal fusion: a review. *Neurosurg* 2000 Nov;47(5):1041-56.
23. Rubin C, et al. The use of low-intensity ultrasound to accelerate the healing of fractures. *J Bone Joint Surg Am* 2001 Feb;83-A(2):259-70.
24. Ryaby JT. Clinical effects of electromagnetic and electric fields on fracture healing. *Clinical Orthopaedics and Related Research* 1998 Oct;355S:S205-15.

25. Satter S, Islam MS, Rabbani KS, et al. Pulsed electromagnetic fields for the treatment of bone fractures. *Bangl Med Research Counc Bull* 1999 Apr;25(1):6-10.
26. Sharrard WJW. A double-blind trial of pulsed electromagnetic fields for delayed union of tibial fractures. *Journal of Bone and Joint Surgery (British)*. 1990;72-B(3):347-355
27. Warden SJ, Bennell KL, McMeeken JM, et al. Acceleration of fresh fracture repair using the sonic accelerated fracture healing system (SAFHS): A review. *Calcif Tissue Int*. 2000;66:157-163.

**Mandated Benefit/Regulatory Issues:**

- Ø Federal
- Ø Commonwealth of Massachusetts
- ⊕ Medicare – National Policy
- ⊕ Medicare – Local Medical Review Policy
- Ø Not applicable

**Committee Review Dates:**

**Technology Assessment Committee:** 11/2000, 01/2001, mm/yyyy

**Utilization Management Committee:** 06/2003, mm/yyyy

Approved by:

---

Dennis A. Batey, M.D., Vice President and Chief Medical Officer

Date