Electrical stimulators for bone growth fall into one of two categories: invasive or noninvasive.

- Invasive bone growth stimulators, also called implantable electrical stimulators, utilize a direct current that is delivered internally via implanted electrodes to a non-healing fracture or bone fusion site.
- Noninvasive systems utilize treatment coils situated externally around the fracture and an external power supply. Noninvasive bone growth stimulators deliver an electrical current to the fracture site via capacitive coupling, pulsed electromagnetic field (PEMF), or combined magnetic field technology. The goal of applying electrical energy to the bone is to induce osteogenesis, which will then stimulate bone growth and promote fracture healing.

Ultrasound stimulation is a noninvasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. It is covered as medically reasonable and necessary for the treatment of established nonunion of a fracture when documented by a minimum of 2 sets of radiographs separated by a minimum of 90 days and when documented to promote accelerated fracture healing (excluding fractures of the skull or vertebrae and tumor-related fractures).

The diagnosis of fracture nonunion is based on pain and motion at the fracture site and on findings using radiography, fluoroscopy, intraosseous venography, technetium scintigraphy, or magnetic resonance imaging that show no visible signs of healing (defined as no progression of callous formation or lack of callous formation for 90 days as determined by serial radiographs), continued fracture gap of less than 1.0cm, and the fracture site has been adequately immobilized. In addition, the member must comply with weight bearing restrictions.

**Policy Statement**
Coverage will be provided for bone growth stimulators when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

**Benefit Application**
Please refer to the member’s individual Evidence of Coverage (E.O.C.) for benefit determination. Coverage will be approved according to the E.O.C. limitations, if the criteria are met.
Coverage decisions will be made in accordance with:
- The Centers for Medicare & Medicaid Services (CMS) national coverage decisions;
- General coverage guidelines included in original Medicare manuals unless superseded by operational policy letters or regulations; and
- Written coverage decisions of local Medicare carriers and intermediaries with jurisdiction for claims in the geographic area in which services are covered.

Benefit payments are subject to contractual obligations of the Plan. If there is a conflict between the general policy guidelines contained in the Medical Coverage Policy Manual and the terms of the member’s particular Evidence of Coverage (E.O.C.), the E.O.C. always governs the determination of benefits.

**CRITERIA REQUIRED FOR COVERAGE APPROVAL**
Preauthorization by the Plan is required prior to the stimulator being dispensed by the vendor;

**AND**

A documented care plan indicating the stimulator use and expected outcome must be submitted by the physician;

**AND**

Documentation of one of the following conditions:
1. Long bone fracture nonunion, when serial radiographs have established that fracture healing has ceased for 3 or more months prior to starting electrical stimulation therapy. *Serial radiographs must include a minimum of 2 sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days*;
2. Failed fusion, where a minimum of 9 months has lapsed since the last surgery;
3. Congenital pseudarthroses;
4. Adjunct to spinal fusion for patients at high risk of pseudarthrosis due to previously failed spinal fusion at the same site or for patients undergoing multiple level fusion, which involves 3 or more vertebrae;
5. Scaphoid nonunion fractures.
6. Jone’s fracture of the 5th metatarsal.

**WHEN COVERAGE WILL NOT BE APPROVED**
1. Conditions that do not meet the coverage criteria.
2. Non-unions of the skull, vertebrae, and those that are tumor-related are excluded from coverage.

**BILLING/ CODING/PHYSICIAN DOCUMENTATION INFORMATION**
This policy may apply to the following codes. Inclusion of a code in the section does not guarantee that it will be reimbursed.

*Applicable Codes: Osteogenic Stimulator: E0747, E0748, E0760  
CPT codes: 20974, 20975, 20979, E0749*

The Plan may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient
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documentation unless all specific information needed to make a medical necessity determination is included.

SPECIAL NOTES
1. Osteogenic units are purchased and worn until healing occurs.
2. Ultrasound therapy must not be used in conjunction with any other noninvasive osteogenic stimulation devices.

References:
1. Medicare National Coverage Determination for Osteogenic Stimulators (ID #150.2); Effective date: 8/1/05: Accessed via Internet site www.cms.hhs.gov/mcd/viewncd on 5/12/09.
2. Medicare Local Coverage Determination for Osteogenesis Stimulators_(ID#L5012); Effective date: 06/01/2007; Accessed via Internet site www.cms.hhs.gov/mcd/viewlcd on 5/12/09.

Policy Implementation/Update Information:
Revision Date: January 8, 2002; January 10, 2002; February 23, 2005; August 24, 2005
November 30, 2006: Revised to include CPT codes 20974, 20975, and 20979. Clarified when ultrasound stimulation is covered.
Clarified definition of “visible signs of healing.” Added “Jones fracture of the 5th metatarsal” under criteria for coverage.
September 2009: No changes proposed to the review criteria. Formatting and minor wording changes only.

Approval Dates:
Medical Coverage Policy Committee: June 2, 2009
Physician Advisory Group (PAG) Committee: September 21, 2009
Quality Improvement Committee (QIC): October 21, 2009

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