

Benefit Coverage

Covered Benefit for lines of business including:
Health Benefits Exchange (HBE), Rite Care (MED), Children with Special Needs (CSN), Substitute Care (SUB), Rhody Health Partners (RHP), Rhody Health Expansion (RHE), and Medicare-Medicaid Plan (MMP) Integrity.
Excluded from Coverage:
Extended Family Planning (EFP)

Description & Definitions

An electrical osteogenesis stimulator is a device that provides electrical stimulation to augment bone repair. *It can be either noninvasive, semi-invasive or invasive* A noninvasive electrical stimulator is characterized by an external power source which is attached to a coil or electrodes placed on the skin or on a cast or brace over a fracture or fusion site. It may use direct current or pulsed electromagnetic fields. An invasive or semi-invasive stimulator uses direct current delivered internally to the fracture site via implanted electrodes.

An ultrasonic osteogenesis stimulator is a noninvasive device that emits low intensity, pulsed ultrasound in an attempt to accelerate the healing time of a fracture.

A multilevel spinal fusion is one which involves 3 or more vertebrae (e.g. L3-L5, L4-S1, etc.).

Examples of long bones include the appendicular skeleton, plus the clavicle. The clavicle is included for ultrasound stimulators but excluded for electronic stimulators.

Non-union is defined as failure of progression of normal healing within a defined period of ninety (90) days. (Documented by serial radiographic documentation separated by not less than thirty [30] days.)

Coverage Determination

Requires Authorization	<ol style="list-style-type: none"> Bone Growth Stimulators are a clinical option when determined medically necessary by Neighborhood's Medical Management Department. <u>Prior authorization is required.</u>
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Criteria

Non-spinal Electrical Osteogenesis Stimulator

ONE of the following criteria must be met:

- Nonunion of a long bone fracture defined as radiographic evidence that fracture healing has not occurred after at least three or more months prior to requesting the osteogenesis stimulator. **OR**

▶ **NOTE:** Non-union of a long bone fracture must be documented by a minimum of two sets of radiographs, including initial fracture, and subsequent radiographs not less than 90 days after injury, along with a written interpretation which documents that there has not been clinically significant evidence of fracture healing between those sets of radiographs.

- Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery. **OR**
- Congenital pseudoarthrosis

Spinal Electrical Osteogenesis Stimulator

ONE of the following criteria must be met:

- Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, **OR**
- Following a multilevel spinal fusion surgery (*see definitions above*), **OR**
- Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site, **OR**
- As an adjunct to spinal fusion to prevent failure in a high risk patient, defined by:
History of current or recent (1 year)
 1. Alcohol or tobacco abuse, **OR**
 2. Diabetic status, **OR**
 3. Renal failure, moderate or severe, **OR**
 4. Grade III or worse spondylolisthesis or
 5. Rheumatoid or other inflammatory type of arthritis, **OR**
 6. History of one or more failed spinal fusions.

Ultrasonic Osteogenesis Stimulator

For non-union in skeletally mature members, **ALL** of the following criteria must be met:

- Fracture gap is one centimeter or less, **AND**
- A minimum of two (2) sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied by a written interpretation by a physician stating that there have been no clinically significant evidence of fracture healing between the two (2) sets of radiographs.

For Tibia Diaphyseal, Radial Diaphyseal, Ulnar Diaphyseal, Distal Radius(Colles), Scaphoid or 5th Metatarsal Fractures Ultrasonic Osteogenic Stimulator is also covered for fresh fractures when:

- Used as an adjunct to conventional management, i.e. closed reduction and cast immobilization, **AND**
- For skeletally mature members with risk factors for poor or prolonged healing, including but not limited to smoking, steroid therapy, diabetes or osteoporosis. **AND**
- The device is applied within the first 14 days.

The ultrasonic osteogenic stimulator may not be used concurrently with other noninvasive osteogenic devices.

Authorization Forms

Please access Prior Authorization forms by visiting Neighborhood's website at www.nhpri.org.

1. Go to the section for Providers
2. Click on "Resources & FAQ's"
3. Click on "Medical Management Request Forms"- forms are listed alphabetically by program.

[Prior Authorization Forms](#)

For assistance with prior authorizations please contact Clinical Administrative Support at 401-459-6060. Fax authorization forms to 401-459-6023.

For More information on Coding please reference the [Authorization Quick Reference Guide](#)

Exclusions

Use of an ultrasonic osteogenic stimulator is excluded for the treatment of:

- A fresh fracture (other than outlined above) or delayed union (3 months or less from initial fracture)
- Skull or vertebrae fractures
- Fractures due to bone malignancy
- Delayed union
- Skull or vertebra or sternum,
- Open fractures,
- Pathologic fractures i.e. malignancy,
- Femur fractures where BMI exceeds 35,
- Fractures outside the diaphysis i.e. central half of bone,
- Fractures with displacement >50%,
- Fractures with internal or external fixation,
- Open fractures – any bone,
- Skeletally immature,
- Pregnant or nursing,
- Implanted electronic devices: i.e. pacemaker, vagus nerve stimulator,
- Non-union treated by bone graft and/or internal/external fixation

CMP Cross Reference:

Created:

Annual Review Month: September

Review Dates: 9/13/06, 9/02/08, 3/09/10, 3/02/11, 5/08/12, 9/16/14, 5/19/15,
5/04/16, 5/17/17, 9/19/18

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**Medical Director Approval
Dates:** 09/01/02, 4/12/07, 9/09/08, 3/09/10, 5/12/11, 10/31/12, 10/8/14
6/8/15, 5/25/16, 6/7/17, 9/19/18

Effective Dates: 09/01/02, 4/12/07, 9/09/08, 3/09/10, 5/12/11, 10/31/12, 10/8/14
6/8/15, 5/31/16, 7/01/16, 6/12/17, 9/19/18

Neighborhood reviews clinical medical policies on an annual base.

Disclaimer:

This medical policy is made available to you for informational purposes only. It is not a guarantee of payment or a substitute for your medical judgment in the treatment of your patients. Benefits and eligibility are determined by the member's coverage plan; a member's coverage plan will supersede the provisions of this medical policy. For information on member-specific benefits, call member services. This policy is current at the time of publication; however, medical practices, technology, and knowledge are constantly changing. Neighborhood reserves the right to review and revise this policy for any reason and at any time, with or without notice.

References:

Snyder, BM et al, "Does Low-Intensity Pulsed Ultrasound Reduce Time to Fracture Healing? A Meta-Analysis", Am J Orth 2012;41(2): E12-E19.

CMS, "National Coverage Analysis for Ultrasound Stimulation for Nonunion Fracture Healing: Invasive Electrical Bone Growth Stimulator," revised 3/15/2011. Accessed 4/20/2016.