Clinical Medical Policy
Bone Growth Stimulators

Benefit Coverage:
Conditional benefit; approval is based on review of medical necessity documentation.

Description:
An electrical osteogenesis stimulator is a device that provides electrical stimulation to augment bone repair. 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.

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 are clavicle, humerus, radius, ulna, femur, tibia, and fibula.

Non-union is defined as the point at which healing has stopped and further healing has ceased for three or more months (as evidenced by serial radiographic documentation.)

Coverage Determination:
Bone Growth Stimulators are a clinical option when determined medically necessary by the Medical Management Department. **Prior authorization is required**.

Criteria – Non-spinal electrical osteogenesis stimulator
One of the following criteria must be met:
1. Nonunion of a long bone fracture defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator.
NOTE: Nonunion of a long bone fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple views of the fracture site, and with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

2. Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery.

3. Congenital pseudoarthrosis.

Criteria – Spinal electrical osteogenesis stimulator

One of the following criteria must be met:
1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery.

2. Following a multilevel spinal fusion surgery (see definitions above).

3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the
same site.

4. As an adjunct to spinal fusion to prevent failure in a high risk patient, defined by:
- Current ETOH or tobacco use, or
- Diabetes or Renal Disease, or
- Degenerative osteoarthritis, or
- Grade III or worse spondylolisthesis

Criteria – Ultrasonic Osteogenesis Stimulator
For non-union in skeletally mature members, all of the following criteria must be met:

1. Fracture gap is one centimeter or less, and

2. A minimum of two 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 has been no clinically significant evidence of fracture healing between the two sets of radiographs.

For Tibia Diaphyseal Fractures which are short oblique or short spiral, and are fresh closed or Grade I, all of the following criteria must be met:

1. Used as an adjunct to conventional management, i.e. closed reduction and cast immobilization, and

2. For skeletally mature members with risk factors for poor or prolonged healing, including smoking, steroid therapy, diabetes and osteoporosis.

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

- A fresh fracture (other than tibial diaphysis) or delayed union (recent fracture 3 months or less from initial fracture)
- Skull or vertebrae fractures
- Fractures due to bone malignancy

CMP Number: CMP-001.01
CMP Cross Reference:

References:

1.) Centers for Medicare and Medicaid Services (CMS). Decision memo for ultrasound stimulation for nonunion fracture healing (CAG-00022R). Medicare Coverage Database. Baltimore, MD: CMS; April 27, 2005. Available at: http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=135.

2.) NHIC, Corp. Medicare Part B Contractor. DME MAC Jurisdiction A, Medical Policies (Local Coverage Determinations): http://www.medicarenhic.com/dme/medical_review/mr_lcds/mr_lcd_current/lcd%20for%20osteogenesis%20stimulators%201206%2Eshtml

3) BCBSRI Clinical Policy for Electrical Bone Growth Stimulators, 7/6/2010 https://www.bcbsri.com/BCBSRIWeb/plansandservices/services/medical_policies/ElectricalBoneGrowthStimulation.jsp

4) Tufts Health Plan coverage Guidelines,Bone Growth Stimulation – Ultrasound, 4/1/2010 http://www.tuftshealthplan.com/providers/pdf/mng/Bone_Growth_Stimulators-Ultrasound_DME.pdf

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