ELECTRICAL AND ULTRASOUND BONE GROWTH STIMULATORS

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INSTRUCTIONS FOR USE

This protocol provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Evidence of Coverage (EOC)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this protocol. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Protocol. Other Protocols, Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Protocols, Policies and Guidelines as necessary. This protocol is provided for informational purposes. It does not constitute medical advice. This policy does not govern Medicare Group Retiree members.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COMMERCIAL COVERAGE RATIONALE

Two MCG™ Care Guidelines, 21st edition, 2017 are identified, one for electrical and electromagnetic bone growth stimulators, and one for ultrasonic bone growth stimulators.


Clinical Indications

Electrical or electromagnetic bone growth stimulators may be indicated when ALL of the following are present:
• Bone growth stimulator is being used as adjunctive treatment to lumbar spine fusion.
• Risk factors for fusion failure are present, as indicated by 1 or more of the following:
  o Comorbid condition associated with compromised bone healing (e.g., diabetes, obesity, osteoporosis, current tobacco use)
  o Multilevel fusion
  o Previous failed fusion
  o Spondylolisthesis grade II or greater

Inconclusive or Non-Supportive Evidence
For acute fractures, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A systematic review and pooled analysis identified 2 randomized controlled trials that studied the effects of electromagnetic stimulation on acute long-bone healing. One study found that electromagnetic stimulation had a benefit (although not statistically significant) in terms of union rates in patients with a femoral neck fracture as compared with those treated with osteosynthesis with 3 screws. The other study did not find any benefit of electromagnetic stimulation on redisplacement rates in women with extra-articular Colles fracture as compared with unblinded controls. The authors concluded that there was insufficient evidence to support use of this technology to improve union rates in fresh fractures. A systematic review and network meta-analysis identified 3 trials evaluating the effect of electrical stimulation on fresh fracture healing and found no significant effect on union rates at 3, 6, or 12 months. A systematic review and meta-analysis of 13 randomized controlled trials (737 patients) that studied pulsed electromagnetic fields and low-intensity pulsed ultrasound bone growth stimulation in patients with acute fractures found no significant difference with either modality in reducing the incidence of nonunion. However, results suggested that electrical or ultrasound stimulation may result in a significant benefit in time to radiologic union in patients undergoing nonoperative treatment and for fractures of the upper limb only. A randomized controlled trial of 43 patients with acute tibial stress fractures found that capacitively coupled electric field stimulation, as compared with placebo, did not accelerate clinical healing. A randomized, double-blind, placebo-controlled, multicenter study of 53 patients with unilateral undisplaced acute scaphoid fracture found no positive effect of adding pulsed electromagnetic fields to conservative treatment consisting of immobilization in a cast; neither time to clinical and radiologic union nor functional outcome differed significantly between treatment and placebo groups. A randomized, double-blind, placebo-controlled, multicenter trial of 102 patients with a unilateral undisplaced acute scaphoid fracture found that the overall time to clinical and radiologic healing (as determined by CT scan) did not differ significantly between the active pulsed electromagnetic fields group and the conservatively treated placebo group. A multicenter double-blind randomized trial that evaluated fresh tibial shaft fractures in 259 patients demonstrated that pulsed electromagnetic field stimulation did not prevent secondary surgical interventions for delayed union or nonunion, and did not improve radiologic union or patient-reported functional outcomes. Given that most studies have variable methodological quality, small sample sizes, and heterogeneous study designs and outcome measurements, further large, well-conducted, randomized controlled trials using standardized devices and treatment protocols are needed.

For cervical spine surgery, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A retrospective case control pilot study of 16 patients undergoing para-axial cervical spine arthrodesis who were at high risk for nonunion found that treatment including implantable direct current stimulation resulted in
fusion in 94% of patients; however, the small sample size led the authors to conclude that further investigation was warranted to define the possible therapeutic role of this type of bone growth stimulator. A randomized controlled trial of 323 patients undergoing anterior cervical diskectomy and fusion revealed that postoperative pulsed electromagnetic field therapy significantly improved fusion rate at 6 months, but not at 12 months; there were no significant differences between intervention and control subjects in terms of pain scores, neck disability index, or Short Form Health Survey (SF-12) scores at either 6 or 12 months.

For delayed union or nonunion of fractures, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A technology assessment concluded that while fracture nonunions heal in patients treated with pulsed electromagnetic fields, direct current, or capacitive coupling stimulation, the effects of the stimulators could not be separated from the effect of concomitant fracture site stabilization. A systematic review and pooled analysis identified 4 trials that studied the effects of electromagnetic stimulation on a total of 106 delayed unions and suggested that electromagnetic stimulation may have a benefit (although the pooled relative risk was not statistically significant and had wide confidence intervals). The authors concluded that there was insufficient evidence that electromagnetic stimulation improved the rate of union in patients with delayed union or nonunion. Another systematic review identified the same 4 trials and concluded that the available evidence, which suggested that electromagnetic field stimulation may offer some benefit in the treatment of delayed union and nonunion of long-bone fractures, is still inconclusive and insufficient to inform clinical practice. A prospective cohort study of 44 patients who received pulsed electromagnetic fields for treatment of tibial shaft delayed union or nonunion found that fracture union was confirmed in 77% of cases; however, there was not a statistically significant association between duration of pulsed electromagnetic field application and probability of increased union. A prospective randomized controlled trial of 58 patients with long-bone fractures and delayed union after surgical reduction and fixation found that early application of pulsed electromagnetic field treatment (for a mean duration of 4.8 months) led to a fracture union success rate of 77%, which was significantly higher than that of the sham control group (48%). Given that most studies have variable methodological quality, small sample sizes, and heterogeneous study designs and outcome measurements, further large, well-conducted, randomized controlled trials using standardized devices and treatment protocols are needed.

For spondylolysis, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A review article identified only case reports of the use of external electrical stimulation for treatment of young athletes with spondylolysis. Further studies of higher methodological quality and larger sample sizes are needed.

*** End of MCG

For information regarding medical necessity review of ultrasonic bone growth stimulators, when applicable, see MCG™ Care Guidelines, 21st Edition 2017, Bone Growth Stimulators, Ultrasonic ACG: A-0414 (AC).

**MCG™ Care Guidelines: Bone Growth Stimulators, Ultrasonic ACG: A-0414 (AC).**

**Clinical Indications**

Ultrasonic bone growth stimulators may be indicated for **1 or more** of the following:
Acute fracture or osteotomy, and need for adjunctive treatment, as indicated by ALL of the following:

- Acute fracture, as indicated by **1 or more** of the following:
  - Fifth metatarsal (Jones) fracture
  - Radial shortening osteotomy
  - Radius fracture treated with plaster immobilization
  - Scaphoid fracture
  - Tibial osteotomy for distraction osteogenesis
  - Tibial shaft fracture, either closed or grade I open, treated with plaster immobilization
  - Ulnar shortening osteotomy
- Fracture reduced and immobilized
- Potential for impaired fracture healing due to clinical risk factors or fracture location (e.g., complex fracture, significant comorbidities, smoking, corticosteroid use)
- No infection at fracture site
- No malignancy at fracture site
- Patient skeletally mature

Delayed fracture or osteotomy healing, as indicated by **ALL** of the following:

- Bone loss 15 mm or less
- Fracture reduced and immobilized
- Less than 6 months since most recent operation
- Long bone fracture or tibial osteotomy
- No clinical or radiographic signs of progress toward healing for 3 or more months
- No malignancy at fracture site
- Patient skeletally mature

**Inconclusive or Non-Supportive Evidence**

For clavicle fractures (acute), evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. A multicenter, double-blind, randomized, placebo-controlled trial of 101 adult patients with a nonoperatively treated fresh clavicle shaft fracture showed that low-intensity pulsed ultrasound had no effect on clinical healing (including the parameters of clinical healing time; time to resumption of daily activities, sports, or professional work; and pain scores or use of pain medication).

*** End of MCG***

**MEDICARE COVERAGE RATIONALE**

Medicare covers electrical and ultrasonic osteogenic stimulators when criteria are met. Refer to the National Coverage Determination for Osteogenic Stimulators (150.2). Medicare has a Local Coverage Determination for Nevada for Osteogenesis Stimulators (L33796) (Accessed April 2017).

**Osteogenic Stimulators (NCD 150.2)**

**General**

An ultrasonic osteogenic stimulator 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. The ultrasonic osteogenic stimulators are not be used concurrently with other non-invasive osteogenic devices.
Indications and Limitations of Coverage

Electrical Osteogenic Stimulators
Nationally Covered Indications

1. Noninvasive stimulator
   The noninvasive stimulator device is **covered** only for the following indications:
   - Nonunion of long bone fractures;
   - Failed fusion, where a minimum of 9 months has elapsed since the last surgery;
   - Congenital pseudarthroses;
   - Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis 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).
   - Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
   - Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. 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. Invasive (Implantable) Stimulator
   The invasive stimulator device is **covered** only for the following indications:
   - Nonunion of long bone fractures;
   - Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high risk of pseudarthrosis 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).
   - Effective September 15, 1980, nonunion of long bone fractures is considered to exist only after 6 or more months have elapsed without healing of the fracture.
   - Effective April 1, 2000, nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for 3 or more months prior to starting treatment with the electrical osteogenic stimulator. 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.

Ultrasonic Osteogenic stimulators
Nationally Covered Indications

Effective January 1, 2001, ultrasonic osteogenic stimulators are **covered** as medically reasonable and necessary for the treatment of nonunion fractures. In demonstrating non-union fractures, CMS expects:

- A minimum of 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 with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs; and
• Indications that the patient failed at least one surgical intervention for the treatment of the fracture.
• Effective April 27, 2005, upon reconsideration of ultrasound stimulation for nonunion fracture healing, CMS determines that the evidence is adequate to conclude that noninvasive ultrasound stimulation for the treatment of nonunion bone fractures prior to surgical intervention is reasonable and necessary. In demonstrating non-union fractures, CMS expects:
• A minimum of 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 with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

Non-Covered Indications
- Nonunion fractures of the skull, vertebrae and those that are tumor-related are excluded from coverage.
- Ultrasonic osteogenic stimulators may not be used concurrently with other non-invasive osteogenic devices.
- Ultrasonic osteogenic stimulators for fresh fractures and delayed unions remain non-covered.

Osteogenesis Stimulators (L33796)
A non-spinal electrical osteogenesis stimulator (E0747) is covered only if any of the following criteria are met:
1. Nonunion of a long bone fracture (see Appendices section) defined as radiographic evidence that fracture healing has ceased for three or more months prior to starting treatment with the osteogenesis stimulator, or
2. Failed fusion of a joint other than in the spine where a minimum of nine months has elapsed since the last surgery, or
3. Congenital pseudoarthrosis

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.

A non-spinal electrical osteogenesis stimulator will be denied as not medically necessary if none of the criteria above are met.

A spinal electrical osteogenesis stimulator (E0748) is covered only if any of the following criteria are met:
1. Failed spinal fusion where a minimum of nine months has elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery (see Appendices section), or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site.
A spinal electrical osteogenesis stimulator will be denied as **not medically necessary** if none of the criteria above are met.

An ultrasonic osteogenesis stimulator (E0760) is **covered only** if all of the following criteria are met:

1. Nonunion of a fracture 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 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; and
2. The fracture is not of the skull or vertebrae; and
3. The fracture is not tumor related.

An ultrasonic osteogenesis stimulator will be denied as **not medically necessary** if any of the criteria above are not met.

Use of an ultrasonic osteogenesis stimulator for the treatment of a fresh fracture or delayed union will be denied as **not medically necessary**.

Ultrasound conductive coupling gel is **covered** and separately payable if an ultrasonic osteogenesis stimulator is **covered**.

An ultrasonic osteogenesis stimulator will be denied as **not medically necessary** if it is used with other noninvasive osteogenesis stimulators.

**For Medicare and Medicaid Determinations Related to States Outside of Nevada:**
Please review Local Coverage Determinations that apply to other states outside of Nevada. [http://www.cms.hhs.gov/mcd/search](http://www.cms.hhs.gov/mcd/search)

**Important Note:** Please also review local carrier Web sites in addition to the Medicare Coverage database on the Centers for Medicare and Medicaid Services’ Website.

### MEDICAID COVERAGE RATIONALE


**Non-spinal noninvasive electrical osteogenesis stimulator may be covered** if:

1. Non-union of a long bone fracture after six months have elapsed without healing of the fracture, **or**
2. Failed fusion of a joint, other than in the spine, where a minimum of nine months have elapsed since the last surgery, **or**
3. Congenital pseudarthrosis.

Required documentation includes:
- Prescription
- Medical documentation supporting qualifying factors.
Note: Rental is for 20-week intervals, additional authorization will be considered with medical justification.

Electric Implantable and Ultrasonic osteogenic stimulators are non-covered Medicaid services.

**Spinal noninvasive electrical osteogenesis stimulator may be covered if:**
1. Failed spinal fusion where a minimum of nine months have elapsed since the last surgery, or
2. Following a multilevel spinal fusion surgery involving three or more vertebrae, or
3. Following spinal fusion surgery where there is a history of a previously failed spinal fusion.

Required documentation includes:
- Medical documentation supporting qualifying factors, and
- Prescription

Note: Rental is for 20-week intervals, additional authorization will be considered with medical justification.

Electric Implantable and Ultrasonic osteogenic stimulators are non-covered Medicaid services.

**BACKGROUND**

Electrical and electromagnetic stimulators have been used to treat fractures and improve healing following spinal fusion surgery. Three types of electrical stimulation technologies are available: direct current, capacitive coupling, and inductive coupling such as pulsed electromagnetic fields. Some direct current technologies require surgical implantation of the device, whereas inductive coupling and capacitive coupling technologies are noninvasive.

External ultrasonic stimulators, also referred to as low-intensity pulsed ultrasound, have been used as adjunctive treatment for acute fracture and in the treatment of delayed union of long-bone fractures. Ultrasonic stimulation is a self-administered, low-time-consuming treatment.

For delayed union and nonunion, the overall success rate of low-intensity pulsed ultrasound is approximately 67% for humerus, 90% for radius/radius-ulna, 82% for femur and 87% for tibia/tibia-fibula.

**U.S. FOOD AND DRUG ADMINISTRATION (FDA)**

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Coverage Determination Guidelines may apply.

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<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (nonoperative)</td>
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<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
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<tr>
<td>20979</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
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* CPT® is a registered trademark of the American Medical Association.

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Corporate Medical Affairs Committee

The foregoing Health Plan of Nevada/Sierra Health & Life Health Operations protocol has been adopted from an existing UnitedHealthcare coverage determination guideline that was researched, developed and approved by the UnitedHealthcare Coverage Determination Committee.