ELECTRICAL AND ULTRASOUND
BONE GROWTH STIMULATORS

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Table of Contents

Table of Contents                               Page

COMMERCIAL COVERAGE RATIONALE................................. 1
MEDICARE COVERAGE RATIONALE.................................. 5
MEDICAID COVERAGE RATIONALE.................................. 8
BACKGROUND................................................................ 8
U.S. FOOD AND DRUG ADMINISTRATION (FDA).................... 9
APPLICABLE CODES..................................................... 9
PROTOCOL HISTORY/REVISION INFORMATION............... 10

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.

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, 19th edition, 2015 are identified, one for electrical and electromagnetic bone growth stimulators, and one for ultrasonic bone growth stimulators.

Electromagnetic Bone Growth Stimulators
Bone Growth Stimulators, Electrical and Electromagnetic ACG: A-0565 (AC).

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:
  - Comorbid condition associated with compromised bone healing (e.g., diabetes, obesity, osteoporosis, current tobacco use)
  - Multilevel fusion
  - Previous failed fusion
  - Spondylolisthesis grade II or greater

Criteria
For lumbar spine fusion, the available evidence supports the use of direct current stimulation or capacitive coupling for enhancing fusion rates in high-risk patients undergoing posterolateral lumbar fusion, and pulsed electromagnetic fields stimulation as an adjunct in similar patients treated with lumbar interbody fusion procedures. Patients with one or more of the following risk factors are considered high-risk for failure of fusion: previous failed fusion, grade II or greater spondylolisthesis, multilevel fusion, or comorbid condition associated with compromised bone healing (e.g., diabetes, obesity, and smoking). A meta-analysis considered 5 randomized controlled trials involving direct current, capacitive coupling, and pulsed electromagnetic fields technologies used after spine fusion. The authors concluded that the pooled results demonstrated the efficacy of electrical stimulation with various modalities on healing times in patients with spinal fusion.

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 of 7 meta-analyses reported that 4 meta-analyses suggested that evidence was insufficient to conclude that electromagnetic stimulation improves the rate of union in patients with a fresh fracture, osteotomy, delayed union, or nonunion; however, the other 3 meta-analyses suggested a more significant treatment effect from electrical stimulation. For fresh fracture, osteotomy, delayed union, or nonunion of long-bone fractures, including tibial stress fractures, a meta-analysis of 11 randomized controlled trials of variable quality did not show a significant benefit of electromagnetic stimulation for treatment of long-bone fractures. 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 of these fractures; neither time to clinical and radiological union nor functional outcome differed significantly between treatment and placebo groups. A randomized controlled trial of 43 patients found that capacitively coupled electric field stimulation did not accelerate acute tibial stress fracture clinical healing. A multicenter double-blind randomized trial that evaluated fresh tibial shaft fractures failed to demonstrate any clinical or functional benefit to justify the use of pulsed electromagnetic field stimulation as an adjunct to the standard care of such fractures; specifically, pulsed electromagnetic field stimulation did not prevent secondary surgical interventions for delayed union or nonunion, and did not improve patient-reported functional outcomes. Large, well-conducted, randomized controlled trials using patient-important outcomes with standardized devices and treatment protocols are needed before these modalities can be accepted for treatment of long-bone fractures.
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 study of 16 high-risk patients undergoing para-axial cervical spine arthrodesis found implantable direct current stimulation to be safe and efficacious; however, the small sample size led the authors to conclude that further investigation was warranted to define the possible role of this type of bone growth stimulator in select patients at high risk for nonunion. 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. (RG B) A systematic review of 7 meta-analyses reported that 4 meta-analyses suggested that evidence was insufficient to conclude that electromagnetic stimulation improves the rate of union in patients with a fresh fracture, osteotomy, delayed union, or nonunion; however, the other 3 meta-analyses suggested a more significant treatment effect from electrical stimulation. For fresh fracture, osteotomy, delayed union, or nonunion of long-bone fractures, including tibial stress fractures, a meta-analysis of 11 randomized controlled trials of variable quality did not show a significant benefit of electromagnetic stimulation for treatment of long-bone fractures. A prospective study of 44 patients who received pulsed electromagnetic fields for tibial shaft delayed union or nonunion found that fracture union was confirmed in 77.3% of cases but noted that pulsed electromagnetic fields have not been assessed in robust studies of high methodological quality. A meta-analysis 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 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. Large, well-conducted, randomized controlled trials using patient-important outcomes with standardized devices and treatment protocols are needed before these modalities can be accepted for treatment of long-bone fractures.

For spondylolysis, evidence is insufficient, conflicting, or poor and demonstrates an incomplete assessment of net benefit vs harm; additional research is recommended. (RG B) The available evidence does not support external electrical stimulation in the management of spondylolysis patients because too few patients have been studied and the results cannot be generalized to the rest of the population; further studies with more patients and more detailed procedures are needed.

*** End of MCG

**Ultrasonic Bone Growth Stimulators**

For information regarding medical necessity review of ultrasonic bone growth stimulators, when applicable, see MCG™ Care Guidelines, 19th Edition 2015, Bone Growth Stimulators, Ultrasonic ACG: A-0414 (AC).
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 and need for adjunctive treatment, as indicated by ALL of the following:

- Acute fracture, as indicated by 1 or more of the following:
  - Closed distal radius (Colles) fracture of wrist
  - 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

- Impaired fracture healing due to clinical issues or fracture location (eg, proximal pole of scaphoid, Jones fracture)

- No infection at fracture site

- No malignancy at fracture site

- Patient skeletally mature

Delayed fracture 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 [A]

- No clinical or radiographic signs of progress toward healing for 3 or more months [B]

- No malignancy at fracture site

- Patient skeletally mature

Criteria

For acute fracture or osteotomy, evidence demonstrates at least moderate certainty of at least moderate net benefit. A systematic review and meta-analysis found variable-quality (very low to moderate) and conflicting evidence for low-intensity pulsed ultrasound in improving a variety of outcomes among patients with fresh fracture, including acceleration of functional recovery and radiographic healing time. The authors concluded that although overall results are promising, large, blinded trials are needed. A meta-analysis of 5 randomized double-blind sham-controlled trials (with 266 fractures of the tibia, radius, and scaphoid) found that low-intensity pulsed ultrasound reduced mean fracture healing time by 36 days as compared with placebo treatment; however, there was significant heterogeneity of the studies and possible publication bias. A systematic review and meta-analysis identified 7 trials that studied the effects of low-intensity pulsed ultrasound on fresh fractures and determined that the time of third cortical bridging was statistically earlier following therapy; the authors concluded that there was moderate-quality evidence to support its use. A systematic review identified 11 trials that studied the effects of low-intensity pulsed ultrasound on treatment of acute fractures. Pooled results from 8
heterogeneous studies of patients with complete fractures were analyzed in a "worst case" analysis to adjust for incomplete data; analysis showed that there was no significant reduction in time to union with ultrasound treatment, but the authors stated that due to heterogeneity of studies, this could represent a clinically important harm or benefit. A prospective randomized study that included 27 patients who underwent ulnar shortening osteotomy or radial shortening osteotomy found that the group treated with low-intensity pulsed ultrasound had significantly faster mean times, as compared with the control group, to complete cortical union (57 days vs 121 days) and complete endosteal union (76 days vs 148 days).

For delayed fracture or osteotomy healing, evidence demonstrates a net benefit, but of less than moderate certainty, and may consist of a consensus opinion of experts, case studies, and common standard care. Cohort studies and case series have demonstrated that use of low-intensity pulsed ultrasound for treatment of delayed union and nonunion of fractures in long bones can achieve overall success rates that range from 67% to 90%. A systematic review and meta-analysis identified 7 studies of the effect of low-intensity pulsed ultrasound on treatment of delayed unions and nonunions; 6 studies supported the effectiveness of ultrasound treatment, while one study did not. The authors concluded that there was low-quality evidence to support accelerated healing in a variety of long-bone fractures, including tibial osteotomy. A randomized sham-controlled trial of 101 subjects with a tibial delayed union revealed that daily treatment with low-intensity pulsed ultrasound for a period of 16 weeks improved bone healing, as measured by bone mineral density and bone gap on CT scan. A United Kingdom national guideline supports low-intensity pulsed ultrasound for the treatment of long-bone fractures with nonunion.

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 has a National Coverage Determination for Osteogenic Stimulators, NCD 150.2 (Accessed June 2015). Medicare has a Local Coverage Determination for Osteogenesis Stimulators, L11490. The National Coverage Determination and Local Coverage Determination are as follows:

Osteogenic Stimulators (NCD 150.2)

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
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 L11490

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

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

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 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.

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

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**

Medicaid Services Manual, Appendix B Accessed June 2015 (There have been no changes to
coverage since October 2011).

**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:
- Medical documentation supporting qualifying factors, and
- Prescription and/or MD signed PA Form.

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

**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 and/or MD signed PA Form.

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

**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**

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<tr>
<th>CPT® Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>20974</td>
<td>Electrical stimulation to aid bone healing; noninvasive (nonoperative)</td>
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<tr>
<td>20975</td>
<td>Electrical stimulation to aid bone healing; invasive (operative)</td>
</tr>
<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.*

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
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<tr>
<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal applications</td>
</tr>
<tr>
<td>E0748</td>
<td>Osteogenesis stimulator, electrical, noninvasive, spinal applications</td>
</tr>
<tr>
<td>E0749</td>
<td>Osteogenesis stimulator, electrical, surgically implanted</td>
</tr>
<tr>
<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, non-invasive</td>
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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.