BONE GROWTH STIMULATORS

Policy Number: DME 006.12 T2
Effective Date: November 1, 2012

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The services described in Oxford policies are subject to the terms, conditions and limitations of the Member’s contract or certificate. Unless otherwise stated, Oxford policies do not apply to Medicare Advantage enrollees. Oxford reserves the right, in its sole discretion, to modify policies as necessary without prior written notice unless otherwise required by Oxford’s administrative procedures or applicable state law. The term Oxford includes Oxford Health Plans, LLC and all of its subsidiaries as appropriate for these policies.

Certain policies may not be applicable to Self-Funded Members and certain insured products. Refer to the Member’s plan of benefits or Certificate of Coverage to determine whether coverage is provided or if there are any exclusions or benefit limitations applicable to any of these policies. If there is a difference between any policy and the Member’s plan of benefits or Certificate of Coverage, the plan of benefits or Certificate of Coverage will govern.

**CONDITIONS OF COVERAGE**

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<td>'CPT codes 20974, 20975 and 20979.</td>
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For the purposes of this policy, nonunion is considered to exist only when serial radiographs confirm that fracture healing has ceased for 3 or more months. 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.

I. Electrical stimulators (E0747, E0748, E0749)
Bone growth stimulation using noninvasive or invasive electrical stimulators is considered medically necessary when used to facilitate healing of the following:

- Nonunion fractures of the femur, tibia, fibula, humerus, radius or ulna.
- After spinal fusion surgery, when:
  - nonunion exists, or
  - Member has previous fusion failure, or
  - Member requires multiple-level fusion.

II. Ultrasound stimulators (E0760)
Bone growth stimulation using ultrasound stimulators is considered medically necessary when used to facilitate healing of the following:

- Nonunion fractures of the femur, tibia, fibula, humerus, radius or ulna.
- As an adjunct to closed reduction and immobilization for the following fresh fractures:
  - Closed or grade I open tibial fractures.
  - Closed fractures of the distal radius (Colles' fracture).

Bone growth stimulation is not considered medically necessary to facilitate healing of tumor-related fractures.

The safety and effectiveness of electrical stimulation or ultrasound has not been studied in patients with spondylitis, infection, Paget's disease, cancer, diabetes mellitus, renal disease, osteoporosis or other pathological conditions, or in patients lacking skeletal maturity.

Bone growth stimulation is not considered medically necessary to facilitate healing of nonunion fractures in bones other than those listed under criteria sets I and II above.

Although a few small studies, mostly case series of the foot and ankle, suggest that healing may be improved by various methods of bone growth stimulation, results from larger randomized controlled studies are necessary to support the use of these devices in other bones such as the tarsals, metatarsals, carpals and metacarpals.

BACKGROUND

Standard fracture management includes stabilization of the fracture site by internal or external fixation devices, compression devices and/or casting. Delayed union or nonhealing can be caused by many factors. Diagnosis of fracture nonunion is based on pain and motion at the fracture site and on findings of imaging studies. Bone healing may be induced and enhanced through the use of bone grafting or by exposure of the fracture site to electrical or ultrasound energy.

Electrical bone growth stimulators are categorized as invasive, semi-invasive or noninvasive. Invasive and semi-invasive devices utilize direct current that is delivered internally via implanted electrodes, with the cathode placed at the fracture site. For invasive systems, the power source is implanted in nearby soft tissue, to be removed at the end of treatment. For semi-invasive systems, the cathodes are inserted percutaneously under fluoroscopic guidance, and the power source is incorporated into the cast. Noninvasive devices may utilize direct current, alternating
currents or pulsed, electromagnetic fields. The current is delivered to the appropriate site via externally mounted cathodes, in the case of direct current, or coils, in the case of electromagnetic fields. Most systems are equipped with monitors to assess the system's function and patient compliance.

Ultrasound (US) devices provide a low-intensity, pulsed, micro-mechanical force to the fracture site. The limb is placed in a cast and a window is created in the cast to allow placement of the transducer on the skin at the fracture site. Treatment consists of one 20-minute session per day until the fracture is healed.

While it is not clear what factors initiate the natural bone repair process, it has been found that electrical potentials are produced in bones that are mechanically under compression or tension due to deformation, and are actively involved in the generation of new bone. It is speculated that bone remodeling is mediated by these electrical potentials, and that electrochemical reactions and products are triggers for the mechanisms of cellular response. The mechanism by which pulsed ultrasound speeds fracture repair is not known. It has been speculated that the pressure waves generated by ultrasound may mediate biological activity either directly by deformation of cell membranes, or indirectly by an electrical effect caused by cell deformation, and that bone formation can be stimulated by electrical and electromagnetic fields of appropriate configuration.

Research:

**Invasive Direct-Current Electrical Stimulation (DCES):** Four case series using implantable stimulation treatment for bone growth were performed. Sample sizes ranged from 12 to 62 and all studies treated patients with nonunion long bone fractures. Overall success rates of subjects achieving bone union ranged from 43.5% to 90% with a mean of 82%. Jenis et al. (2000) conducted a randomized, controlled trial of 61 patients evaluating instrumented spinal fusion alone or in combination with either DCES or pulsed electromagnetic field (PEMF) therapy. The investigators found no discernible difference between DCES, PEMF and placebo in spinal fusion.

**Noninvasive Direct-Current Electrical Stimulation:** One double blind, placebo-controlled study was reviewed where capacitive coupling was used to treat nonunion tibia, ulnar or femur fractures (Scott, 1994). The randomized sample of 21 patients showed that 60% of active patients and none of placebo patients achieved fracture union. Steinberg et al. randomized patients exhibiting Steinberg stage I-III avascular necrosis (AVN) of the femoral head receiving decompression and grafting to active or inactive capacitive coupling units (Steinberg et al. 1989). Results at a mean follow-up period of 31 months showed that 42% of the hips in the active group and 50% in the placebo group were improved or unchanged; Harris scores dropped from 94 to 82 in the active group and increased from 75 to 76 in the placebo group. The authors concluded that capacitive coupling did not add any additional benefit to decompression and grafting in the treatment of AVN. Abeed et al. reported that 68.7% of a sample of 16 nonunion long bone fractures of at least 9 months duration, healed with capacitive coupling treatment, with a mean healing time of 15 weeks (Abeed, 1998).

**Pulsed Electromagnetic Fields (PEMF):** Two double-blind, placebo-controlled studies treated nonhealing tibial fractures with PEMF. In one, forty-five patients were randomized to active or placebo treatment for 12 weeks. Radiological assessment revealed 5 completed unions, 5 progressing toward union, and 10 nonunions in the treatment group; and 1 union, 1 progressing towards union, and 23 nonunions in the placebo group. Orthopaedic surgeons assessed 9 unions and 11 nonunions in the treatment group, and 3 unions and 23 nonunions in the placebo group (Sharrard, 1990). Complications were not reported. In the second trial of 34 patients with tibial fractures, x-ray confirmed bony fusion in 88.9% of the treated group and 50% of the placebo group (Simonis, 2003).

One double-blind, placebo-controlled study examined whether the use of PEMF accelerated the healing of freshly fused vertebrae (Mooney, 1990). Mooney randomized 195 patients to either PEMF or sham treatment and found that success was significantly higher in the PEMF group.
Mooney also found the success rate for patients treated with PEMF more than or equal to 4 hours per day was comparable with outcomes in the placebo group.

Eight case series were reported using PEMF to treat delayed or nonhealing fractures (Adams, 1992, Bassett, 1982, Colson, 1998, Connolly, 1981, Cook, 1997, Kloczynski, 1988, Madronero, 1988, Mammi, 1993) and osteonecrosis of the femoral head (Bassett, 1982). Among the 7 studies treating delayed or nonunion long-bone fractures with PEMF, the mean healing rate was 74.75%. In the study describing PEMF treatment of osteonecrosis, no hips classified as Steinberg stage III progressed and 9 of 15 improved, but 18 of 79 stage IV hips progressed and none improved, and 1 of 21 stage V hips worsened while none improved. One study treated nonunion of scaphoid fractures with PEMF and casting, either until healing occurred, or for at least 3 months duration. Overall healing rate was reported to be 69%.

**Combined Electromagnetic Field Stimulation (CMF):** CMF combines a dynamic magnetic field superimposed over a static magnetic field. Few studies have been conducted on this modality. In a study of 201 patients with noninstrumented posterolateral fusions, adjunctive use of CMF electrical stimulation increased the 9-month success of spinal fusion in the female study population, but not in the male population. Fusion success rates in the active and placebo groups were 64% versus 43%, respectively, for all patients, and 58.5% versus 55% for males and 67% versus 35% for females (Linovitz, 2002).

In a randomized controlled trial (RCT), Paillard et al. analyzed the physiological effects of electrical stimulation vs. voluntary muscle contraction exercise vs. both activities combined in 32 postmenopausal women (Paillard, 2005). They concluded that the three groups adapted differently on some parameters of bone mineral density and dynamic strength. The device was not identified in the abstract.

**Direct-Current (DC) Stimulation:** One randomized controlled study evaluated DC stimulation treatment for femoral head avascular necrosis (AVN) and found improved healing in the DC stimulation group compared with the non-DC group (Steinberg et al. 1998). A case series using DC to treat long bone nonunion fractures reported that 17 of 22 nonunions (77.3%) achieved solid osseous union (Brighton, 1985).

**Ultrasound (US) Bone Growth Stimulation:** Two randomized, double blind, placebo-controlled studies using ultrasound to accelerate the healing of fresh fractures were performed. Kristianson et al. (1997) found that ultrasound produced significantly accelerated rates to early trabecular healing, bridging of the first, second, third, and fourth bridged cortices, loss of reduction, and time to union for radial fractures than did the placebo group. Additionally, ultrasound was found to significantly reduce the healing time of fresh tibial shaft fractures in both smokers and nonsmokers. Additionally, follow-up performed several years after the study found that 100% of patients that were located remained healed.

Leung et al. (2004) randomly assigned 30 complex tibial fractures to treatment with low-intensity pulsed ultrasound stimulation or a placebo. The US treated group showed statistically significantly better healing by clinical, radiological, densitometric and biochemical assessment. Each group had one case of delayed union.

Handolin et al. published 3 RCTs (n=22, n=30, n=16) on what appears to be overlapping patient groups. Patients had lateral malleolar fractures treated with or without low-intensity ultrasound 20 minutes for 42 days. In all three trials, there was no obvious effect of low-intensity ultrasound on lateral malleolar fracture healing (Handolin, 2005a, 2005b, 2005c).

In a RCT of 21 patients with osteoarthritis and varus deformity in both knees, Tsumaki et al. (2004) treated one limb with low-intensity ultrasound for four weeks. The mean increase in callus bone mineral density was significantly greater in the treated limbs.

Two retrospective case series studied nonunions in patients at least 9 months of age who failed prior therapy. Overall healing rates ranged from 84% to 100% and were significantly higher.
compared with the self-paired control of failed treatment (Mayr, 2000, Nolte, 2001). In cases of delayed union in patients at fracture age 3 to 9 months, healing rates were also statistically significant and ranged from 87% to 98%. Healing rates for both delayed unions and nonunions peaked for patients who were between 30 to 50 years old.

**Miscellaneous studies:** Saxena et al. (2005) conducted a retrospective, multicenter review of 26 patients who underwent 28 forefoot and hindfoot arthrodeses. Criteria defining patients as "high risk" included diabetes, obesity, habitual tobacco and/or alcohol use, immunosuppressive therapy, and previous history of nonunion. Standard arthrodesis protocol of bone graft and internal fixation was supplemented with the implantable electrical bone stimulator. Radiographic consolidation was achieved in 24 of the 28 cases at an average 10.3+/−4.0 weeks. Followup averaged 27.2 months. Complications included 2 patients who sustained breakage of the cables to the bone stimulator. Five patients underwent additional surgery. Four of the 5 patients had additional surgery in order to achieve arthrodesis. All 4 went on to subsequent arthrodesis. Study design, lack of control and small patient population limit the results.

Saltzman, et al. (2004) retrospectively examined the results of pulsed electromagnetic field (PEMF) treatment for delayed healing after foot and ankle arthrodesis. Of three hundred and thirty-four foot and ankle arthrodeses, nineteen resulted in delayed unions that were treated with a protocol of immobilization, limited weightbearing and PEMF stimulation for a median of 7 (range 5 to 27) months. The protocol was successful in 5 of 19 (26%) patients. Of the other 14 patients with nonunions, nine had revision surgery with autogenous grafting, continued immobilization, and PEMF stimulation. Seven of these eventually healed at a median of 5.5 (range 2 to 26) months and two did not heal. One patient had a below-knee amputation, and four refused further treatment. The authors found that this protocol had a relatively low success rate in this group of patients and no longer use it to treat delayed union after foot and ankle arthrodesis.

Dhawan et al. (2004) evaluated PEMF in a consecutive series of 64 patients undergoing hindfoot arthrodesis in 144 joints. Patients undergoing elective triple/subtalar arthrodesis were randomized into control and PEMF groups. As confirmed by x-ray, average time to union in the control group was 24.5 weeks in 33 primary subtalar arthrodeses. There were 4 nonunions. The study group consisted of 22 primary subtalar arthrodeses and 5 revisions. Average time to union was 12.9 weeks. Average time to fusion of the joint in the control group was 17.6 weeks in 19 primary procedures. Average time to fusion in the PEMF group was 12.2 weeks.

In a review of proximal fifth metatarsal fractures, Rosenberg and Sferra (2000) reported a successful union rate between 72% and 93% following standard treatment with non-weight-bearing cast immobilization. Delayed unions and nonunions can be managed with operative fixation with either closed axial intramedullary-screw fixation or autogenous corticocancellous grafting. Early results with the use of electrical stimulation are promising; however, prospective studies are needed to better define the role of this modality in managing these injuries.

**Additional Product Information:**

EBI OsteoGen (EBI, Biomet), Physio-Stim Lite and Spinal-Stim Lite (Orthofix), Dynatron STS (Dynatronics Corp.), Cervical-Stim (Orthofix, Inc.), Exogen (Smith and Nephew).

**APPLICABLE CODES**

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the Member’s plan of benefits or Certificate of Coverage. This list of codes may not be all inclusive.
Applicable CPT Codes

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<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>
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<tr>
<td>20979</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
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Applicable HCPCS Code:

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<tr>
<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal applications</td>
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<td>E0748</td>
<td>Osteogenesis stimulator, electrical, noninvasive, spinal applications</td>
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<td>E0749</td>
<td>Osteogenesis stimulator, surgically implanted</td>
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<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, non-invasive</td>
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REFERENCES

The foregoing Oxford policy has been adapted from an existing UnitedHealthcare national policy that was researched, developed and approved by the UnitedHealthcare national Medical Technology Assessment Committee.


**POLICY HISTORY/REVISION INFORMATION**

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<td>- Routine review; reorganized policy content (no change to language/guidelines)</td>
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