AmeriHealth Caritas has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas will update its clinical policies as necessary. AmeriHealth Caritas’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas considers the use of bone growth stimulators to be clinically proven and, therefore, medically necessary when all of the following criteria are met for each category (non-invasive electrical stimulators, invasive electrical stimulators, and ultrasonic osteogenic stimulators for nonunion fractures):

Electrical osteogenic stimulators

1. Noninvasive stimulators:
   - Nonunion of long bone fractures, only after six or more months without healing of the fracture, or only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator.
   - Failed fusion, where a minimum of nine months has elapsed since the last surgery.
   - Congenital pseudarthroses.
• 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 three or more vertebrae (e.g., L3 – L5 or L4 – S1).

2. Invasive (implantable) stimulators:

• Nonunion of long bone fractures.
• 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 three or more vertebrae (e.g., L3 – L5 or L4 – S1).
• Nonunion of long bone fractures is considered to exist only after six or more months have elapsed without healing of the fracture.
• Nonunion of long bone fractures is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator.

3. Ultrasonic osteogenic stimulators for nonunion fractures:

• A minimum of two sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days.
• Indications that the patient failed at least one surgical intervention for the treatment of the fracture (Centers for Medicare & Medicaid Services, 2005).

Limitations:

The following are considered investigational and, therefore, not medically necessary:

• 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 remains non-covered (Centers for Medicare & Medicaid Services, 2005).

Contraindications to electrical bone growth stimulation include synovial or metaphyseal pseudarthroses, fracture gaps > 1 centimeter or necrotic ends, or significant motion at the site that is difficult to control. Electrical bone growth stimulators should be avoided in patients with cancer, those who are pregnant, or who have permanent pacemakers. Additional contraindications include infection at the site, disorders of bone metabolism, severe osteoporosis, and avascularity at the site. Patients with rheumatoid arthritis, nutritional defects, those who are taking corticosteroids, or who are noncompliant are inappropriate candidates (InterQual, 2018.1).

Alternative covered services:

Surgical or closed reduction with casting.
Background

Bone fractures are a common event, and 5 percent – 10 percent show delayed healing or nonunion. Approaches to delayed or non-healing include bone-stimulation devices using ultrasound or electrical stimulation, the use of which has grown sharply in recent years.

Direct current electrical stimulation, also known as osteogenic stimulation, involves surgical implants of multiple cathodes are surgically implanted either in or proximate to the fracture or osteotomy site. A constant current is delivered through a battery-powered anode placed on the patient’s skin over the fracture. After the battery expires in six to eight months, the cathodes are removed.

Capacitive coupling is a non-invasive approach to delivering a current at the site of the fracture. Electrodes placed on the skin on either side of the bone deliver a constant current to the fracture site through an external capacitor. The process involves periodic battery changes.

Inductive coupling, or pulsed electromagnetic field, is a third means of bone growth stimulation for non-healed fractures. Low-intensity pulsed ultrasound is a commonly used device that uses ultrasonic mechanical pulses. The treatment is non-invasive, and involves patients wearing pulsed electromagnetic field devices over surgical dressings, splints, or casts, and delivers widespread pulsed electrical charges, with no direct skin contact. Patients typically use the units for three to 10 hours per day (Haglin, 2017).

Searches

AmeriHealth Caritas searched PubMed and the databases of:
- UK National Health Services Center for Reviews and Dissemination.
- Agency for Healthcare Research and Quality.
- The Centers for Medicare & Medicaid Services.
- Cochrane reviews.

We conducted searches on January 17, 2019. Search terms were: "non-healing fractures," "osteogenic stimulator," and "bone growth stimulator device."

We included:
- Systematic reviews, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- Guidelines based on systematic reviews.
- Economic analyses, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.
Findings

The Centers for Medicare & Medicaid Services issued a National Coverage Determination in 2005 describing conditions for which bone growth stimulators for fractures are considered reimbursable by Medicare (Centers for Medicare & Medicaid Services, 2005).

A guideline for the use of bone growth stimulators as an adjunct for lumbar fusion compared direct current stimulation, pulsed electromagnetic field stimulation, and capacitive coupled electrical stimulation. Direct current stimulation is recommended for patients younger than age 60, but not for patients over age 60, due to lack of documented positive outcomes (Kaiser, 2014).

A review of four guidelines showed a large disparity of recommendations for use of electrical stimulation in treating vertebral compression fractures (Parriera, 2017).

A systematic review of six randomized controlled trials of patients who underwent spinal fusion surgery documented that compared to placebo or no stimulation, electric stimulation did not improve the process of fusion after nine to 24 months of follow-up (Park, 2014). A systematic review of 21 articles (n = 1381) of spinal fusion patients revealed that capacitive coupling, inductive coupling, and direct current were associated with similar positive outcomes in fusion rates (Tian, 2013).

A Cochrane review of four trials (n = 125) of delayed union or non-union long bone fractures failed to yield conclusive evidence of improvement in pain reduction and functional outcome measures. The small sample size and statistical heterogeneity also contributed to the inability to provide significant results (Griffin, 2011).

A systematic review of 27 eligible trials that included patients with a fresh fracture suggested benefit of low-intensity pulsed ultrasound at six months. In patients with an existing nonunion or delayed union, electrical stimulation had a suggested benefit over standard care on union rates at three months. The study concluded that there is only very low-quality evidence suggesting a potential benefit of low-intensity versus electrical stimulation in improving union rates at six months in fresh-fracture populations (Ebrahim, 2014).

A narrative review of electrical stimulation to enhance bone healing by Griffin identified 105 clinical studies and 35 in vitro studies of the technology. Direct current was found to be effective in enhancing bone healing in spinal fusion and the authors supported its use for nonunions. Eleven studies were retrieved for capacitive coupling demonstrating its effectiveness for treating nonunions. The majority of studies used inductive coupling, supporting its application for healing osteotomies and nonunions. Overall, the studies, although in favor of electrical stimulation application in bone repair, displayed variability in treatment regime, primary outcome measures, follow-up times, and study design, making critical evaluation and assessment difficult (Griffin, 2011).
A systematic review of low-intensity pulsed ultrasound for nonunion fractures included 13 studies (n = 1,441). The pooled estimate of effect size for health rate was significant for any fracture site, at a fracture age of at least three months (82 percent, P < .001) and eight months (84 percent, P < .001). The authors conclude that low-intensity pulsed ultrasound represents a feasible alternative to surgery for fracture nonunions (Leighton, 2017). Another systematic review found that outcomes for non-healing fractures were superior for low-intensity pulsed ultrasound, compared to low-level laser therapy (Bayat, 2018).

A systematic review of 24 randomized trials (n = 429) of fracture patients given low-intensity pulsed ultrasound revealed an average reduction in healing time of fractures of 39.8 days (considered effective), but that there was no improvement in functional recovery (Rutten, 2016).

A systematic review of 13 studies (n = 737) showed improvement in fracture patients after both pulsed electromagnetic fields and low-intensity pulsed ultrasound, but only in non-operatively treated fractures or fractures of the upper limb (Hannemann, 2014).

A systematic review of the effects of low-intensity pulsed ultrasound on regeneration of fractured bone included 23 studies, seven of which were eligible for meta-analysis. The time of third cortical bridging was statistically faster following therapy in fresh fractures (Bashardoust Tamali S, 2012).

Alternatively, a systematic review of 26 randomized controlled trials (n = 1,610) found that outcomes of low-intensity pulsed ultrasound for nonunion fractures of the tibia or clavicle did not differ from controls. Outcomes included time to return to work, number of subsequent operations, days to weight bearing, days to radiographic healing, and pain (Schandelmaier, 2017).

A systematic review determined that smoking reduces bone mineral density (Al-Bashaireh, 2018). A study of 120 adults who underwent direct current bone stimulation found that healing time is delayed in smokers, along with deep soft tissue infection or osteomyelitis (Hughes, 2010).

**Policy updates:**

A total of two guidelines/other and 11 peer-reviewed references were added to, and five guidelines/other and five peer-reviewed references removed from this policy in January 2019.

The clinical policy number was changed from CP#14.02.03 to CCP.1119 in January 2019.

**References**

**Professional society guidelines/other:**

InterQual®: CP: Bone Growth Stimulators – noninvasive.


Peer-reviewed references:


**Centers for Medicare & Medicaid Services National Coverage Determinations:**

Osteogenic stimulators. 150.2


**Local Coverage Determinations:**
No Local Coverage Determinations identified as of the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Codes</th>
<th>Description</th>
<th>Comments</th>
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<tbody>
<tr>
<td>20974</td>
<td>Electrical stimulation to aid in bone healing, noninvasive.</td>
<td></td>
</tr>
<tr>
<td>20975</td>
<td>Electrical stimulation to aid bone healing, invasive (operative)</td>
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</tr>
<tr>
<td>20979</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
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<tr>
<td>97035</td>
<td>Application of a modality to one or more areas; ultrasound, each 15 minutes</td>
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<th>ICD-10 Codes</th>
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<td>M80.011K-M80.079K</td>
<td>Age-related osteoporosis with current pathological fracture, subsequent encounter for fracture with nonunion</td>
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<tr>
<td>M80.811K-M80.879K</td>
<td>Other osteoporosis with current pathological fracture, subsequent encounter for fracture with nonunion</td>
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<td>M84.411K-M84.4173K</td>
<td>Pathological fracture, subsequent encounter for fracture with nonunion</td>
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<td>M84.619K-M84.673K</td>
<td>Pathological fracture in other disease, unspecified shoulder, subsequent encounter for fracture with nonunion</td>
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<td>M96.0</td>
<td>Pseudoarthrosis after arthrodesis or fusion</td>
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<td>S42.413K-S42.96XK</td>
<td>Fracture with subsequent encounter for fracture with nonunion</td>
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<td>S49.001K-S49.199K</td>
<td>Fracture of humerus with subsequent encounter with nonunion</td>
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<td>S52.019K-S62.92XK</td>
<td>Fracture of ulna, wrist or hand with subsequent encounter for nonunion</td>
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<td>S72.001K-S79.199K</td>
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<td>S82.101K-S89.399K</td>
<td>Fracture lower leg with subsequent encounter for nonunion</td>
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<td>Z98.1</td>
<td>Arthrodesis status</td>
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<th>HCPCS Codes</th>
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<td>E0760</td>
<td>Osteogenesis stimulator, low intensity ultrasound, non-hypheninvasive</td>
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<tr>
<td>E0747</td>
<td>Osteogenesis stimulator, electrical, noninvasive, other than spinal application.</td>
</tr>
<tr>
<td>E0748</td>
<td>Osteogenesis stimulator, electrical, noninvasive, spinal application.</td>
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<tr>
<td>E0749</td>
<td>Osteogenesis stimulator, electrical, surgically implanted.</td>
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