



*Easy Choice Health Plan*

*Missouri Care*

*'Ohana Health Plan, a plan offered by WellCare Health Insurance of Arizona*

*OneCare (Care1st Health Plan Arizona, Inc.)*

*Staywell of Florida*

*WellCare (Arizona, Arkansas, Connecticut, Florida, Georgia, Illinois, Kentucky, Louisiana, Mississippi, Nebraska, New Jersey, New York, South Carolina, Tennessee, Texas)*

*WellCare Prescription Insurance*

*WellCare Texan Plus (Medicare – Dallas & Houston markets)*

## Osteogenic Stimulation

Policy Number: HS-019

Original Effective Date: 5/2/2008

Revised Date(s): 7/16/2009; 7/28/2010;  
8/2/2011; 7/5/2012 (retired); 7/11/2014;  
6/5/2015; 9/15/2016; 12/7/2017; 11/1/2018

### APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

### DISCLAIMER

The Clinical Coverage Guideline (CCG) is intended to supplement certain standard WellCare benefit plans and aid in administering benefits. Federal and state law, contract language, etc. take precedence over the CCG (e.g., Centers for Medicare and Medicaid Services [CMS] National Coverage Determinations [NCDs], Local Coverage Determinations [LCDs] or other published documents). The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this CCG. Additionally, CCGs relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. Providers are responsible for the treatment and recommendations provided to the member. The application of the CCG is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations, and any state-specific Medicaid mandates. Links are current at time of approval by the Medical Policy Committee (MPC) and are subject to change. Lines of business are also subject to change without notice and are noted on [www.wellcare.com](http://www.wellcare.com). Guidelines are also available on the site by selecting the Provider tab, then "Tools" and "Clinical Guidelines".

### BACKGROUND

Of the estimated 5.6 million fractures that occur annually in the United States, approximately 5% to 10% will demonstrate signs of delayed or impaired healing. The healing of a bone fracture is a complex process that can be influenced by many factors. Standard management of fractures includes stabilization of the fracture site with internal or external fixation devices, compression devices, and/or casting. In some cases, insufficient blood supply, inadequate immobilization at the fracture site, too large a gap between ends of the fracture, infection, bone-tissue loss, poor nutrition, osteoporosis, or metabolic dysfunctions can interfere with normal healing and result in delayed union or nonunion of the fracture. Diagnosis of fracture nonunion is based on clinical findings of motion, pain, and tenderness at the fracture site and on findings from radiography, fluoroscopy, intraosseous venography, or bone scintigraphy. Treatment of nonunion generally consists of further or enhanced stabilization of the fracture site and

the induction of osteogenesis. Stabilization is achieved with a cast or with internal or external fixation devices in order to realign and closely approximate fracture fragments, and bone grafts may be used to induce osteogenesis. Other methods available are those that are designed to stimulate bone growth, such as electrical or low-intensity pulsed ultrasound (US) therapy.

#### *Ultrasonic (US) Osteogenic Stimulation*

In ultrasonic (US) osteogenic stimulation, mechanical energy is transmitted into the body as high-frequency acoustic pressure waves that apply micromechanical stresses and strain to the bone and surrounding tissues. While the exact mechanisms are unclear, US causes biochemical changes at the cellular level that promote and accelerate bone formation, and thus, fracture healing. US therapy is used in conjunction with the stabilization of fresh fractures or as secondary therapy for nonunions that remain unhealed after surgery and other therapies. The only devices currently approved by the Food and Drug Administration (FDA) for treating specific bone fractures are three models of the Sonic Accelerated Fracture Healing System (SAFHS®) (Smith & Nephew, Exogen, Memphis, TN). The patient uses the US device, which is prescribed by a physician, at home for 20 minutes once daily until healing occurs.

US therapy safely and effectively enhances the fracture healing process at the cellular, radiological, and clinical level. At-home use of the SAFHS device accelerates fracture healing when used in conjunction with closed reduction and cast immobilization for the treatment of selected patients with fresh fractures of the tibia or radius that are treated within 7 days post fracture. There is insufficient evidence to conclude that US therapy is useful for any other type of fresh fracture. While none of the studies examined the effects of US therapy on functional outcomes or quality of life, accelerated healing of uncomplicated, fresh fractures would result in a shorter period of immobilization, a more expedient return to normal activities, avoidance of the need for additional treatments, and reduced healthcare and related costs. These positive effects are most pronounced in patients with a higher risk of delayed healing or nonunion, such as smokers, older patients, or those with certain comorbidities.

US therapy also promotes fracture healing in patients with nonunions with a fracture age > 9 months and in those with delayed unions with a fracture age of 3 to 9 months in whom healing has ceased or is not progressing. While there are some differences in healing rates among types of bones, the overall healing rates in patients with previously unhealed and poorly healing fractures were 84% to 100%, respectively. US therapy promotes healing in complicated cases, such as those with metal implants or with fractures > 3 years old. None of the studies systematically evaluated the impact of US therapy on functional outcomes or quality of life. However, it can be concluded that any therapy that promotes healing of an unhealed fracture that is refractory to all other reasonable therapeutic options, including surgery, would decrease the need for extensive, costly therapies and rehabilitation, and allow patients to return to their normal activities, thereby improving quality of life.

#### *Electrical Osteogenic Stimulation*

The clinical use of electrical stimulation for inducing osteogenesis at bone fracture and bone fusion sites began in the early 1970s. While the precise mechanism by which electrical energy may promote bone healing is not known, it is known that electrical potentials are produced in bone that is actively involved in the formation of new bone. Electrical bone growth stimulators fall into one of three categories: invasive, semi-invasive, or noninvasive. Invasive and semi-invasive devices, also called implantable electrical stimulators, utilize direct current that is delivered directly to the fracture site via implanted electrodes. Noninvasive systems utilize treatment coils situated externally around the fracture and an external power supply. Noninvasive bone growth stimulators deliver electrical current to the fracture site via capacitive coupling, pulsed electromagnetic field (PEMF), or combined electromagnetic field (CMF) technology.

Available evidence from the relatively small, randomized, placebo-controlled trials and uncontrolled studies suggests that noninvasive electrical bone growth stimulation, particularly when delivered via PEMF, can stimulate healing of long bone fracture nonunion. However, due to lack of sufficient data, no definitive conclusions can be drawn regarding the efficacy of noninvasive electrical stimulation for nonunions of appendicular bones other than long bones. There also is some evidence to support the efficacy of noninvasive electrical stimulation as an adjunct to surgery for spinal fusion, however, the evidence is less consistent, while most studies suggest a benefit, one shows no improvement in fusion rates and one provides equivocal evidence. Evidence from studies involving capacitive

coupling is not as strong as for PEMF since, in part, there are fewer studies evaluating this modality, translating into fewer total number of patients enrolled in capacitive coupling trials, and none of the studies have been published more recently than 1999. Furthermore, there are some inconsistencies in results. Finally, the evidence is sparser for CMF, only two studies have been published, and both reported positive findings; one was a moderate-sized, multicenter randomized controlled trial that evaluated CMF as adjunctive treatment in patients undergoing lumbar spinal fusion.

Implantable electrical bone growth stimulators are FDA-approved for the treatment of nonunion of long bone fractures and as an adjunct to spinal fusion in patients at high-risk of pseudarthrosis due to previously failed spinal fusion at the same site or who require multilevel fusion.

## POSITION STATEMENT

### Applicable To:

- Medicaid
- Medicare

NOTE: Market-specific criteria are listed at the end of the Position Statement section of this document. Please refer to it for any Medicaid related requirements and/or exclusions.

### Exclusions (for all types of devices)

Osteogenic devices are excluded from coverage for the following:

- Nonunion fractures of the skull, vertebrae and those that are tumor-related.
- Ultrasonic osteogenic stimulators cannot be used concurrently with other non-invasive osteogenic devices.
- Ultrasonic osteogenic stimulators for fresh fractures and delayed unions.

### Coverage

#### Non-Invasive Osteogenesis Stimulator

A non-invasive, non-spinal electrical osteogenesis stimulator **is considered medically necessary** when ANY of the following criteria are met:

1. Non-union of long bone fracture (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, phalanges, metacarpal or metatarsal bone) and at least 90 days have passed since the date of fracture or the date of surgical treatment of the fracture;
  - The bone is non-infected; **AND,**
  - The two portions of the bone involved in the non-union are separated by less than 1 centimeter (cm); **AND,**
  - The bone is stable at both ends by means of a cast or fixation; **AND,**
  - When serial radiographs (X-rays) have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the noninvasive electrical bone growth stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days

**OR,**

2. Failed fusion of a joint other than the spine where a minimum of six months has elapsed since the last surgery (NOTE: A minimum of 6 months applies to Illinois Medicaid); **OR,**

**OR,**

3. Congenital pseudoarthrosis

NOTE: Nonunion of a long fracture must be documented by a minimum of two sets of radiographs obtained prior to starting treatment, 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.

4. As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed fusion surgery or for those undergoing fusion at more than one level;

**OR,**

5. Risk of delayed or non-union of fractures due to the following comorbidities (list may not be all inclusive):
  - Alcoholism
  - Chemotherapy
  - Diabetes
  - Obesity
  - Osteoporosis
  - Renal disease
  - Smoking habit
  - Steroid use

### **Invasive Osteogenesis Stimulator**

A spinal electrical osteogenesis stimulator **is considered medically necessary** if ANY of the following criteria are met:

- Non-union of long bone\* fracture and **ALL** of the following:
  - The bone is non-infected; **AND,**
  - The two portions of the bone involved in the non-union are separated by less than 1 cm; **AND,**
  - The bone is stable at both ends by means of a cast or fixation; **AND,**
  - When serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the invasive bone growth stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days;

**OR,**

- Failed spinal fusion where a minimum of 9 months has elapsed since the last surgery and / or as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis; **OR,**

**OR,**

- Risk of delayed or non-union of fractures due to the following comorbidities (list may not be all inclusive):
  - Alcoholism
  - Chemotherapy
  - Diabetes
  - Obesity
  - Osteoporosis
  - Renal disease
  - Smoking habit
  - Steroid use

**OR,**

- Following a multilevel spinal fusion; **OR,**

**OR,**

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

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## Ultrasonic Osteogenesis Stimulator

### Exclusions

An ultrasonic osteogenesis stimulator **is considered NOT medically necessary**:

- If used with other noninvasive osteogenic stimulators; **OR**,
- Avascular necrosis of the femoral head; **OR**,
- Stress fractures
- Fractures in which the gap exceeds 1 cm.
- Fresh fractures in locations other than distal radius, tibial diaphysis, 5th metatarsal (Jones fracture only) or scaphoid.
- Fresh tibial diaphyseal or tibial and fibular fractures treated with closed reduction and intramedullary nailing and no risk factors for poor or prolonged healing.
- Preoperative use for fractures that require surgical intervention, or internal or external fixation (i.e., use of ultrasonic BGS for fractures in the preoperative period would not be covered).
- Tibial stress fractures.

### Coverage

An ultrasonic osteogenesis stimulator **is considered medically necessary** if ALL of the following criteria are met:

- The fracture is not of the skull or vertebrae; **AND**,
- The fracture is not tumor related

Ultrasonic osteogenesis stimulators **may be considered medically necessary** when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh, closed fractures when there is high risk for delayed fracture healing or nonunion. The member must have at least one of the following risk factors from either category, fracture locations or comorbidities:

- Fractures associated with extensive soft tissue or vascular damage; **OR**,
- Fresh\*, closed or grade I\*\* open, short oblique or short spiral tibial diaphyseal fractures treated with closed reduction and cast immobilization in skeletally mature patients\*\*\*; **OR**,
- Fresh\*, closed fractures of the distal radius (Colles' fracture) treated with closed reduction and cast immobilization in skeletally mature patients\*\*\*; **OR**,
- Fresh\* Jones fracture (5th metatarsal); **OR**,
- Fresh\* fractures of the scaphoid; **OR**,
- Nonunion of bones other than the skull or vertebrae in skeletally mature patients\*\*\*, and excluding those that are related to malignancy when:
  - Documented by a minimum of two sets of radiographs obtained prior to starting treatment, separated by a minimum of 90 days. (**NOTE:** 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**,
  - The patient has failed ≥ 1 surgery and other medical therapies;

**OR**,

- Risk of delayed or non-union of ANY fresh\*, closed fractures due to the following comorbidities (list may not be all inclusive):
  - Alcoholism

- Chemotherapy
- Diabetes
- Obesity
- Osteoporosis
- Renal disease
- Smoking habit
- Steroid use

\*Fresh is considered ≤ 7 days in duration.

\*\*Grade I denotes that the skin opening is one centimeter or less and minimal muscle contusion.

\*\*\*Skeletally mature refers to a system of fused skeletal bones, which occurs when bone growth ceases after puberty; for females, this generally occurs around age 16, and for males, around age 18.

Note: This criteria for bone growth stimulators is not consistent with the Medicare National Coverage Policy, and therefore may not be applicable to Medicare members. Refer to CMS at <http://www.cms.hhs.gov> for details.

### **Market Specific Criteria (Medicaid)**

NOTE: No criteria listed for the following markets: Georgia, Hawaii, Missouri, New Jersey and South Carolina.

#### **FLORIDA**

Medicaid may reimburse for an osteogenesis stimulator when non-union long bone fractures exceed three (3) months, when there is congenital pseudoarthrosis or failed fusion. The treating physician's prescription must specify that less costly alternatives were tried and that the osteogenesis stimulator has been prescribed in lieu of surgery.

#### **ILLINOIS**

Purchase of a non-invasive bone growth stimulator requires submittal of an HFS 1409, Prior Approval Request form. Medical justification must be consistent with current standards of practice.

Required information must include:

1. Requests must include certification of medical necessity by an orthopedic surgeon, neurosurgeon, or podiatrist ordering within the limitations circumscribed by the Illinois Medical Practice Act; **AND**,
2. Date of original injury; **AND**,
3. Diagnosis including grading of spondylolisthesis where relevant; **AND**,
4. Original, serial, and most recent radiographic reports delineating location and type of fracture and degree of gap at fracture site; **AND**,
5. Nature of the precipitating injury; **AND**,
6. Operative reports(s), current and previous at same site; **AND**,
7. Current risk factors for nonhealing such as nicotine use, chronic renal disease, diabetes mellitus, or chronic oral steroid use; **AND**,
8. Serial outpatient progress notes; **AND**,
9. If the patient is a teenager;
  - a. A declaration must be made about the skeletal maturity or supply a radiographic report wherein a comment is made specifically about the epiphyseal growth plate either being open or closed at the fracture site proposed for treatment; **AND/OR**;
10. If the patient has a pacemaker or other implantable cardiac defibrillator that may be negatively affected by the bone growth stimulator, this must be declared.

#### **KENTUCKY**

Noninvasive electric osteogenesis stimulators are covered for purchase only.

## NEW YORK

Ultrasound bone growth stimulators are covered when medically necessary and ordered by a board certified or board eligible orthopedic surgeon for non-union fractures of the tibial shaft as evidenced by: an assessment of why the fracture is non-union, no evidence of healing based on a minimum of three sequential monthly examinations, at least 50% of the fractures are in apposition, no more than ten degrees of anterior or posterior angulation, no more than fifteen degrees of lateral angulation in either varus or valgus, and other contributing factors that would affect bone growth such as age, smoking, etc. Under no circumstances will ultrasound bone growth stimulation be approved for true synovial synarthrosis.

## CODING

### Ultrasonic Osteogenesis Stimulator

#### Covered CPT® Code

**20979** Low intensity ultrasound stimulation to aid bone healing, noninvasive (non-operative)

#### Covered HCPCS Codes

**A4559** Coupling gel or paste, for use with ultrasound device, per oz.

**E0760** Osteogenesis stimulator, low intensity ultrasound, noninvasive

### Electrical Osteogenic Stimulator

#### Covered CPT® Codes

**20974** Electrical stimulation to aid bone healing; non invasive (nonoperative)

**20975** Electrical stimulation to aid bone healing; invasive (operative)

#### Covered HCPCS Code

**A4559** Coupling gel or paste, for use with ultrasound device, per oz.

**E0747** Osteogenesis stimulator; electrical, noninvasive, other than spinal applications

**E0748** Osteogenesis stimulator; electrical, noninvasive , spinal applications

**E0749** Osteogenesis stimulator; electrical, surgically implanted

Coding information is provided for informational purposes only. The inclusion or omission of a CPT, HCPCS, or ICD-10 code does not imply member coverage or provider reimbursement. Consult the member's benefits that are in place at time of service to determine coverage (or non-coverage) as well as applicable federal / state laws.

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## MEDICAL POLICY COMMITTEE HISTORY AND REVISIONS

Date	Action
11/1/2018, 12/7/2017, 9/15/2016, 6/5/2015	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>
9/4/2014	<ul style="list-style-type: none"> <li>• Approved by MPC and now used for coverage determinations (see Position Statement).</li> </ul>
7/5/2012	<ul style="list-style-type: none"> <li>• Retired by MPC; covered by InterQual.</li> </ul>
12/1/2011	<ul style="list-style-type: none"> <li>• New template design approved by MPC.</li> </ul>
8/2/2011	<ul style="list-style-type: none"> <li>• Approved by MPC. No changes.</li> </ul>