



Harmony Behavioral Health, Inc.

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Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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Osteogenic Stimulation

Policy Number: HS-019

Original Effective Date: 5/2/2008

Revised Date(s): 7/16/2009; 7/28/2010;
8/2/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. 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 Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. 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.

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.

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 postfracture. 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

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

- Non union of long bone fracture (i.e., clavicle, humerus, radius, ulna, femur, tibia, fibula, 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; **OR**,
- Failed fusion of a joint other than the spine where a minimum of nine months has elapsed since the last surgery (NOTE: A minimum of 6 months applies to Illinois Medicaid); **OR**,
- Congenital pseudoarthrosis; **OR**,

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.

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

- Failed spinal fusion where a minimum of 9 months has elapsed since the last surgery; **OR**,
- Following a multilevel spinal fusion; **OR**,
- Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site

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

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

Ultrasonic osteogenic 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:

1. Fracture locations:
 - **825.25 or 825.35** Fracture of the metatarsal including Jones fracture (fracture of fifth metatarsal)
 - **814.01 or 814.11** Fracture of the navicular bone or scaphoid in the wrist
 - Numerous Codes Fractures associated with extensive soft tissue or vascular damage.
2. Member co-morbidities:
 - **250.00 - 250.93** Diabetes
 - **V58.65** Long term use of Steroid therapy
 - **733.00** Osteoporosis
 - **305.00 – 305.01** Current heavy alcohol use
 - **305.1** Current smoking on a regular basis

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

- If used with other noninvasive osteogenesis stimulators; **OR**,
- **733.42** Avascular necrosis of the femoral head; **OR**,
- **733.93 - 733.99** Stress fractures

Special Ultrasonic Stimulation Parameters for New York Medicaid

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 (nonoperative)

Covered ICD-9-CM Procedure Code

00.09 Other Therapeutic ultrasound

Covered HCPCS Code

A4559 Coupling gel or paste, for use with ultrasound device, per oz.
E0760 Osteogenesis stimulator, low intensity ultrasound, noninvasive

Covered ICD-9 Diagnosis codes for Ultrasonic Osteogenesis Stimulator – This list may not be all inclusive

733.81 Malunion of fracture
733.82 Nonunion of fracture
738.4 Acquired spondylolisthesis
756.12 Spondylolisthesis
814.01 Closed fracture of navicular (scaphoid) bone of wrist
814.11 Open fracture of navicular (scaphoid) bone of wrist
823.00 Fracture upper end, closed, tibia alone
823.02 Fracture upper end, closed, fibula with tibia
823.10 Fracture upper end, open, tibia alone
823.12 Fracture upper end, open, fibula with tibia
823.20 Fracture shaft, closed, tibia alone
823.22 Fracture shaft, closed, fibula with tibia
823.30 Fracture shaft, open, tibia alone
823.32 Fracture shaft, open, fibula with tibia
823.80 Fracture unspecified part, closed, tibia alone
823.82 Fracture unspecified part, closed, fibula with tibia
823.90 Fracture unspecified part, open, tibia alone
823.92 Fracture unspecified part, open, fibula with tibia
825.25 Closed fracture of metatarsal bone(s)
825.35 Open fracture of metatarsal bone(s)

Non Covered ICD-9 Diagnosis codes for Ultrasound Osteogenic Stimulator

170.4 - 170.8 Malignant neoplasm of scapula and long bones of upper limb, short bones of upper limb, pelvic bones, sacrum, and coccyx, long bones of lower limb, or short bones of lower limb
198.5 Secondary malignant neoplasm of bone and bone marrow
713.5 Arthropathy associated with neurological disorders [Charcot foot/arthropathy]
733.10 - 733.19 Pathologic fracture
733.42 Aseptic necrosis of head and neck of femur
733.93 - 733.99 Stress fractures
800.00 - 804.9 Fracture of skull
805.00 - 806.9 Fracture of vertebral column
996.67 Infection and inflammatory reaction due to other internal orthopedic device, implant, and graft
996.78 Other complications due to internal orthopedic device, implant, and graft

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

Covered ICD-9 Procedure code for Invasive / Operative Electrical Osteogenic Stimulator

78.90 – 78.99 Insertion of Bone Growth Stimulator, specified by site

Covered ICD-9 Diagnosis codes for Electrical Osteogenic Stimulator – This list may not be all inclusive

- 722.81** Postlaminectomy syndrome; Cervical region; failed spinal fusion, failed back syndrome
722.82 Postlaminectomy syndrome; Thoracic region; failed spinal fusion, failed back syndrome
722.83 Postlaminectomy syndrome; Lumbar region; failed spinal fusion, failed back syndrome
733.81 Malunion of fracture
733.82 Nonunion of fracture
738.4 Acquired spondylolisthesis
756.12 Spondylolisthesis
814.01 Closed fracture of navicular (scaphoid) bone of wrist
814.11 Open fracture of navicular (scaphoid) bone of wrist
823.00 Fracture upper end, closed, tibia alone
823.02 Fracture upper end, closed, fibula with tibia
823.10 Fracture upper end, open, tibia alone
823.12 Fracture upper end, open, fibula with tibia
823.20 Fracture shaft, closed, tibia alone
823.22 Fracture shaft, closed, fibula with tibia
823.30 Fracture shaft, open, tibia alone
823.32 Fracture shaft, open, fibula with tibia
823.80 Fracture unspecified part, closed, tibia alone
823.82 Fracture unspecified part, closed, fibula with tibia
823.90 Fracture unspecified part, open, tibia alone
823.92 Fracture unspecified part, open, fibula with tibia
825.22 Closed fracture of navicular (scaphoid), foot
825.25 Closed fracture of metatarsal bone(s)
825.32 Open fracture of navicular (scaphoid), foot
825.35 Open fracture of metatarsal bone(s)

Non Covered ICD-9 Diagnosis codes for Electrical Osteogenic Stimulators

- 713.5** Arthropathy associated with neurological disorders [Charcot foot]
733.42 Aseptic necrosis of head and neck of femur
756.11 Spondylolysis, lumbar region

808.0 - 808.3 Fracture of pelvis
811.00 - 811.19 Fracture of scapula
814.02 & 814.12 Fracture of lunate

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.©©

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HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
8/2/2011	• Approved by MPC. No changes.