Medical Policy Bulletin

Title: Electrical Bone Growth Stimulation and Low-Intensity Ultrasound Accelerated Fracture Healing System

Policy #: 05.00.09h

The below medical or claim payment policy is applicable to the Company’s commercial products only. Policies that are applicable to the Company’s Medicare Advantage products for dates of service on or after 1/01/2015 are accessible via a separate Medicare Advantage policy database.

The Company makes decisions on coverage based on Policy Bulletins, benefit plan documents, and the member’s medical history and condition. Benefits may vary based on contract, and individual member benefits must be verified. The Company determines medical necessity only if the benefit exists and no contract exclusions are applicable.

When services can be administered in various settings, the Company reserves the right to reimburse only those services that are furnished in the most appropriate and cost-effective setting that is appropriate to the member’s medical needs and condition. This decision is based on the member’s current medical condition and any required monitoring or additional services that may coincide with the delivery of this service.

This Medical Policy Bulletin document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged or new medical literature may have been published. This Medical Policy Bulletin will be reviewed regularly and be updated as scientific and medical literature becomes available. For more information on how Medical Policy Bulletins are developed, go to the About This Site section of this Medical Policy Web site.

Intent

The intent of this policy is to communicate the coverage positions for electrical bone growth stimulation and low-intensity ultrasound accelerated fracture healing system.
For information on policies related to this topic, refer to the Cross References section in this policy.

**Description**

**STAGES OF NORMAL BONE HEALING**

Fractured bones go through a natural healing process that includes the growth of both bone mass and bone density. Normal bone healing usually occurs in three stages:

1. **Inflammatory stage:** In this stage, a hematoma forms on the fracture site after the injury. Inflammatory cells infiltrate the bone to form granulation tissue, vascular tissue, and immature tissue. This process will continue for two to four weeks.

2. **Reparative stage:** In this stage, the healing process takes place. The various components needed to build new bone and fill the fracture gap come together to form the "fracture callous." The callous is then replaced with lamellar bone (hard, rigid connective tissue). The lamellar bone is mineralized, causing it to become harder and stronger. The result is called trabecular bone (spongy osseous material), which is vascularized. This process takes from one to two months.

3. **Remodeling stage:** This stage brings about the change of the trabecular bone to a denser, more mature bone. This phase may take up to five years to be completed and is dependent upon the type of bone fractured and the age and health status of the individual.

In approximately five to ten percent of fractured bones, healing is impaired or does not progress at a normal rate. This impaired progression results in continued morbidity by causing the fracture to be at risk for nonunion or delayed union. Delayed union occurs when there is a deceleration in the fracture healing process (as identified by serial radiographic documentation). Nonunion fracture is defined as the point at which healing has stopped, and further healing has ceased for three or more months (as evidenced by serial radiographic documentation). Delayed union differs from nonunion in that, in the former, there are no indications that union will fail, while in the latter, there are no visible signs that union will occur (ie, serial radiographic documentation shows no evidence of healing). Moreover, any fracture type, such as a previously surgically treated fracture, a sesamoid fracture, or a stress fracture (ie, small crack in the bone), can develop into a delayed union or nonunion.

Most, if not all, nonunion fractures require some type of intervention to heal. In some cases, a bone growth stimulator (osteogenesis stimulator) may be used to encourage or reanimate the healing process by physical methods including electrical and low-intensity pulsed ultrasound. Electrical bone growth stimulators provide stimulation through electrodes placed either at or around the fracture site. Studies support the theory that these electrodes produce electromagnetic fields that trigger a small electrical current similar to the signals that the body naturally produces to initiate bone healing. Low-intensity ultrasound accelerated fracture healing system delivered via a special device placed in contact with the skin overlying the fracture site delivers low-intensity pulsed ultrasound waves with the aim of stimulating bone healing. It is proposed that healing is promoted by stimulating the production of growth factors and proteins that include the removal of old bone, increase the production of new bone, and increase the rate at which fibrous matrix at a fracture site is converted to mineralized bone. Studies are ongoing regarding the nature of bone osteogenesis and the application of techniques for applying electrical and low-intensity pulsed ultrasonic fields to promote healing at fracture sites.

**ELECTRICAL BONE GROWTH STIMULATORS**

**INDICATIONS FOR USE OF ELECTRICAL BONE GROWTH STIMULATORS**

Electrical bone growth stimulators have been approved by the US Food and Drug Administration (FDA) for
treatment of the following:

- Nonunion fractures of the appendicular skeleton: fractures with no visible signs of healing, (e.g., cortical and/or trabecular bridging with major modifications of the radiolucent gap) for at least three consecutive months.
- Congenital pseudarthrosis of the appendicular skeleton: congenital disorder of the diaphysis, which is revealed by a pseudarthrosis or "false joint" due to the inability to form a normal callus to bridge the gap following a fracture, and also manifests in bone with modifications such as bowing, narrowing of the medullary canal, or a cyst.
- Failed surgical fusion: unsuccessful fusion, as defined by a surgical fusion that has not healed for a minimum of six months following the original surgery, which may be evidenced by a decrease in cortical and/or trabecular bridging, presence of angulation (motion), or a radiolucent gap.

Although the FDA has approved electrical bone growth stimulators for the cervical spine as an adjunct to cervical fusion surgery in individuals at high risk for a nonunion of the fusion, currently the evidence does not demonstrate that electrical bone growth stimulators, as an adjunct to cervical fusion surgery and for failed cervical spine fusion, improves health outcomes.

There is currently insufficient scientific evidence to support the use of electrical bone growth stimulators for the thoracic spine as an adjunct to thoracic fusion surgery and for failed thoracic spine fusion.

APPLICATION METHODS FOR ELECTRICAL BONE GROWTH STIMULATORS

- Noninvasive: Noninvasive devices may use pulsed electromagnetic fields (PEMFs) that rely on inductive coupling, capacitive coupling, or combined magnetic fields technology to generate the current. An external power supply and externally applied coils or a transducer are placed on skin overlying the fracture and generate a weak electrical current through the site where bone growth is desired. The size of the electric field is dependent on the scale of the magnetic field and the physical qualities of the tissues immediately surrounding the fracture site.

- Invasive: A technique that uses a direct electrical current, with a current generator surgically implanted in an intramuscular or subcutaneous space. The generator is connected to an electrode that is surgically implanted within the bone fragments that need to be fused. The implanted device typically remains functional for six to nine months after implantation. Although the generator is surgically removed when the course of treatment is complete, the electrode may or may not be removed.

- Semi-invasive: A direct current is delivered via electrodes percutaneously placed in the proximity of the site to receive treatment, and the generator is placed on the external surface of the body. Currently, semi-invasive electrical bone growth stimulators are not approved by the FDA.

LOW-INTENSITY ULTRASOUND ACCELERATED FRACTURE HEALING SYSTEM

USES OF LOW-INTENSITY ULTRASOUND ACCELERATED FRACTURE HEALING SYSTEM

Low-intensity ultrasound accelerated fracture healing systems received approval from the FDA as an adjunct treatment to closed reduction and cast immobilization in a skeletal system that has been determined to be mature for the following fracture types:

- Fresh, closed, posteriorly displaced distal radius fractures (Colles fractures)
- Fresh, closed or Grade I open tibial diaphysis fractures

Fresh fractures are most commonly defined as the first seven days from the initial fracture. In addition, a
Grade I open tibial diaphysis fracture is associated with skin breakage or opening of one centimeter (cm) or less. In clinical trials, the use of a low-intensity ultrasonic bone growth stimulator for treatment of fresh fractures of the tibial diaphysis and distal radius demonstrated significantly faster healing times than fractures that were not treated with the system. Fractures of the tibial diaphysis and distal radius are typically associated with a high risk for nonunion.

The FDA has expanded its original approval of low-intensity ultrasound accelerated fracture healing systems to include the treatment of the following fracture types of the appendicular skeleton (i.e., bones of the shoulder girdle, bones of the upper and lower extremities, and bones of the pelvis, excluding the skull and vertebrae):

- Established nonunion fractures
- Delayed union fractures

The safety and effectiveness of low-intensity ultrasound accelerated fracture healing systems have not been established in a skeletal system that is not mature, or in nonunion fractures of the skull and vertebrae.

APPLICATION METHOD FOR LOW-INTENSITY ULTRASOUND ACCELERATED FRACTURE HEALING SYSTEMS

- Noninvasive: Low-intensity ultrasound accelerated fracture healing systems are applied noninvasively to the external surface of the affected body part, over the area to receive the treatment. The exact mechanism of healing is unknown, but it is believed that the ultrasound causes biochemical changes at the cellular level, accelerating bone growth.

Policy

Coverage is subject to the terms, conditions, and limitations of the member's contract.

ELECTRICAL BONE GROWTH STIMULATORS (NONINVASIVE CPT 20974, INVASIVE CPT 20975)

MEDICALLY NECESSARY -- APPENDICULAR SKELETON
Nonunion Fractures and Congenital Pseudarthroses of the Appendicular Skeleton

Noninvasive electrical bone growth stimulators are considered medically necessary and, therefore, covered for the treatment of nonunion fractures (including nonunion of previously surgically treated fractures, nonunion of sesamoid fractures, nonunion of stress fractures), or congenital pseudoarthroses (i.e., a spontaneous fracture which progresses to nonunion) of the appendicular skeleton (i.e., bones of the shoulder girdle, bones of the upper and lower extremities, and the pelvic girdle) when ALL of the following criteria are met:

- Skeletal system is determined to be mature (e.g., as evidenced by hand-wrist radiographs)
- At least 3 months have passed since original fracture date
- Serial radiographs confirm that no progression in healing has taken place
- The fracture gap is one centimeter (cm) or less
- The fracture can be adequately immobilized and a non-weight-bearing status is maintained as appropriate.

Failed Surgical Fusion of Joints of the Appendicular Skeleton

Noninvasive electrical bone growth stimulators are considered medically necessary and, therefore, covered as treatment for failed surgical fusion of joints, of the appendicular skeleton (e.g. wrist, ankle, toe,
shoulder, elbow, hip), as defined by a surgical fusion that has not healed for a minimum of six months following the last surgery, as evidenced by serial radiographs over a course of three months.

MEDICALLY NECESSARY -- LUMBAR SPINE
Failed Lumbar Spinal Fusion and as an Adjunct to Lumbar Spinal Fusion in Individuals at High Risk for Fusion Failure

Noninvasive electrical bone growth stimulators are considered medically necessary and, therefore, covered as treatment for failed lumbar spinal fusion, as defined by a spinal fusion that has not healed for a minimum of six months following the original surgery, as evidenced by serial radiographs over a course of three months.

Invasive and noninvasive electrical bone growth stimulators are considered medically necessary and, therefore, covered as an adjunct to lumbar spinal fusion for individuals at high risk for fusion failure, when one of the following criteria is met:

- Grade III or worse spondylolisthesis
- One or more previous failed spinal fusion(s)
- Fusion to be performed at more than one level
- Individual has one or more of the following comorbidities:
  - Diagnosis of alcoholism
  - Current tobacco use
  - Diagnosis of diabetes
  - Current use of prescribed steroids
  - Diagnosis of osteoporosis
  - Diagnosis of renal disease
  - Current use of prescribed anticoagulation medications

EXPERIMENTAL/INVESTIGATIONAL

All other uses for noninvasive electrical bone growth stimulators of the appendicular skeleton are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature. This includes, but is not limited to, the following:

- Treatment of fresh fractures
- Treatment of delayed union fractures
- Post-surgical treatment after appendicular skeletal surgery without evidence of nonunion
- Treatment of sesamoid fractures without evidence of nonunion
- Treatment of stress fractures without evidence of nonunion
- Treatment of patellar tendinopathy

Invasive and semi-invasive electrical bone growth stimulators of the appendicular skeleton are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature.

Semi-invasive electrical stimulation as an adjunct to lumbar fusion surgery and for failed lumbar fusion is considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature.

Invasive, semi-invasive, and noninvasive electrical stimulation as an adjunct to cervical or thoracic fusion surgery and for failed cervical or thoracic spine fusion is considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the
available published peer-reviewed literature.

All other uses for electrical bone growth stimulators are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature.

LOW-INTENSITY ULTRASOUND ACCELERATED FRACTURE HEALING SYSTEM (E0760)

MEDICALLY NECESSARY -- APPENDICULAR SKELETON

Fresh, Closed Fractures of the Appendicular Skeleton at Risk for Becoming Delayed or Nonunion Fractures

Low-intensity ultrasound accelerated fracture healing systems are considered medically necessary and, therefore, covered as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh, closed fractures of the appendicular skeletal system (i.e., bones of the shoulder girdle, bones of the upper and lower extremities, and bones of the pelvis) that is determined to be mature (e.g., evidenced by hand-wrist radiographs), and is determined to be at high risk for delayed fracture healing or nonunion fractures, that includes having at least ONE of the following indications (i.e., one comorbidity OR one fracture location):

- The individual has one of the following comorbidities:
  - Diagnosis of alcoholism
  - Current tobacco use
  - Diagnosis of diabetes
  - Current use of prescribed steroids
  - Diagnosis of osteoporosis
  - Diagnosis of renal disease
  - Current use of prescribed anticoagulation medications

OR

- The individual has one of the following fracture locations:
  - Fracture of metatarsal, including Jones fracture (5th metatarsal)
  - Navicular bone fracture of the wrist (also known as the scaphoid)
  - Fractures associated with extensive soft tissue or vascular damage

Delayed Union Fractures of the Appendicular Skeleton

Low-intensity ultrasound accelerated fracture healing systems are considered medically necessary and, therefore, covered as a treatment of delayed union fractures (including delayed union of previously surgically treated fractures, delayed union of sesamoid fractures, delayed union of stress fractures) of the appendicular skeleton (i.e., bones of the shoulder girdle, bones of the upper and lower extremities, and the pelvic girdle) that is determined to be mature (e.g., evidenced by hand-wrist radiographs), when ALL of the following criteria are met:

- At least three months have passed since the index injury or the most recent intervention.
- The decelerating healing process is confirmed by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site.

Nonunion Fractures of the Appendicular Skeleton

Low-intensity ultrasound accelerated fracture healing systems are considered medically necessary and,
therefore, covered as a treatment of established nonunion fractures (including nonunion of previously surgically treated fractures), nonunion of sesamoid fractures, nonunion of stress fractures, of the appendicular skeleton (ie, bones of the shoulder girdle, bones of the upper and lower extremities, and the pelvic girdle, when ALL of the following criteria are met:

- Skeletal system is determined to be mature (e.g., evidenced by hand-wrist radiographs).
- At least three months have passed since the original fracture date.
- Serial radiographs confirm that no progression in healing has taken place.
- The fracture gap is one cm or less.
- The fracture can be adequately immobilized, and a non-weight-bearing status is maintained as appropriate.

EXPERIMENTAL/INVESTIGATIONAL
All other uses for low-intensity ultrasound accelerated fracture healing systems, including but not limited to the following, are considered experimental/investigational and, therefore, not covered because their safety and/or effectiveness cannot be established by review of the available published peer-reviewed literature.

- Treatment of open fractures
- Treatment of fractures treated with an open procedure (i.e., ORIF) without evidence of delayed union or nonunion
- Treatment of fresh surgically treated closed fractures
- Treatment of sesamoid fractures without evidence of delayed union or nonunion
- Treatment of stress fractures without evidence of delayed union or nonunion
- Treatment of fractures of the skull or vertebrae
- Treatment of fractures that are tumor-related
- For concurrent use with another noninvasive osteogenic stimulator
- Treatment in a skeletal system determined not to be mature (e.g., evidenced by hand-wrist radiographs)
- Treatment of a spinal fusion
- Treatment of congenital pseudarthroses
- Treatment of an arthrodesis or failed arthrodesis
- Treatment of patellar tendinopathies

REQUIRED DOCUMENTATION
The Company may conduct reviews and audits of services to our members regardless of the participation status of the provider. Medical record documentation must be maintained on file to reflect the medical necessity of the care and services provided. These medical records may include but are not limited to: records from the professional provider’s office, hospital, nursing home, home health agencies, therapies, and test reports. This policy is consistent with Medicare’s documentation requirements, including the following required documentation:

PRESCRIPTION (ORDER) REQUIREMENTS
Before submitting a claim to the Company, the supplier must have on file a timely, appropriate, and complete order for each item billed that is signed and dated by the professional provider who is treating the member. Requesting a provider to sign a retrospective order at the time of an audit or after an audit for submission as an original order, reorder, or updated order will not satisfy the requirement to maintain a timely professional provider order on file.

PROOF OF DELIVERY
Medical record documentation must include a contemporaneously prepared delivery confirmation or
member’s receipt of supplies and equipment. The medical record documentation must include a copy of delivery confirmation if delivered by a commercial carrier and a signed copy of delivery confirmation by member/caregiver if delivered by the DME supplier/provider. All documentation is to prepared contemporaneous with delivery and be available to the Company upon request.

CONSUMABLE SUPPLIES
The durable medical equipment (DME) supplier must monitor the quantity of accessories and supplies an individual is actually using. Contacting the individual regarding replenishment of supplies should not be done earlier than approximately seven days prior to the delivery/shipping date. Dated documentation of this contact with the individual is required in the individual’s medical record. Delivery of the supplies should not be done earlier than approximately five days before the individual would exhaust their on-hand supply.

If required documentation is not available on file to support a claim at the time of an audit or record request, the durable medical equipment (DME) supplier may be required to reimburse the Company for overpayments.

Guidelines

Note: Serial radiographs are defined as at least two sets of appropriate imaging studies separated by a minimum of 90 days or three months, confirming that clinically significant fracture healing has not occurred.

Manufacturer labeling may vary regarding the programming and the operational time frame of the stimulator.

TYPES OF FRACTURES

FRESH FRACTURES
A fresh fracture is commonly defined as “fresh” for around the first seven days from when the fracture occurred. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.

DELAYED UNION FRACTURES
A delayed union fracture can be defined as a decelerating healing process of the bone. It is determined by serial radiographs, together with a lack of clinical and radiologic evidence of union, bony continuity, or bone reaction at the fracture site for at least three months from the initial fracture or the most recent intervention, in which healing has not advanced at the average rate for the location and type of fracture.

NONUNION FRACTURES
A nonunion fracture is considered established when the fracture site shows no visibly progressive signs of healing, for at least three consecutive months from the time of the fracture.

BENEFIT APPLICATION

Subject to the terms and conditions of the applicable benefit contract, bone growth stimulators are covered under the medical benefits of the Company’s products when the medical necessity criteria listed in this medical policy are met.

Services that are experimental/investigational are benefit contract exclusions for all products of the Company.

US FOOD AND DRUG ADMINISTRATION (FDA) STATUS
There are numerous devices approved by the FDA for bone growth stimulation.

References


Foley KT, Mroz TE, Arnold PM, et al. Randomized, prospective, and controlled clinical trial of pulsed


Summary of Safety and Effectiveness Data. Exogen 2008® or Sonic Accelerated Fracture Healing System (SAFHS®). Exogen®, a Smith and Nephew Company, Piscataway, NJ.

US Food and Drug Administration (FDA). Center for Devices and Radiological Health. Cervical-Stim®


**Coding**

Inclusion of a code in this table does not imply reimbursement. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

The codes listed below are updated on a regular basis, in accordance with nationally accepted coding guidelines. Therefore, this policy applies to any and all future applicable coding changes, revisions, or updates.

In order to ensure optimal reimbursement, all health care services, devices, and pharmaceuticals should be reported using the billing codes and modifiers that most accurately represent the services rendered, unless otherwise directed by the Company.

The Coding Table lists any CPT, ICD-9, ICD-10, and HCPCS billing codes related only to the specific policy in which they appear.

> **CPT Procedure Code Number(s)**

<table>
<thead>
<tr>
<th>Procedure Description</th>
<th>Code</th>
</tr>
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<tbody>
<tr>
<td>ELECTRICAL STIMULATION FOR NON-INVASIVE PROCEDURES</td>
<td>20974</td>
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<tr>
<td>ELECTRICAL STIMULATION FOR INVASIVE PROCEDURES</td>
<td>20975</td>
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<td>ULTRASOUND STIMULATION FOR NON-INVASIVE PROCEDURES</td>
<td>20979</td>
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<tr>
<td>EXPERIMENTAL/INVESTIGATIONAL ELECTRICAL STIMULATION FOR SEMI-INVASIVE PROCEDURES</td>
<td>20999</td>
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</tbody>
</table>
Professional and outpatient claims with a date of service on or before September 30, 2015, must be billed using ICD-9 codes. Professional and outpatient claims with a date of service on or after October 1, 2015, must be billed using ICD-10 codes.

Facility/Institutional inpatient claims with a date of discharge on or before September 30, 2015, must be billed with ICD-9 codes. Facility/Institutional inpatient claims with a date of discharge on or after October 1, 2015, must be billed with ICD-10 codes.

ICD - 9 Procedure Code Number(s)
N/A

ICD - 10 Procedure Code Number(s)
N/A

Professional and outpatient claims with a date of service on or before September 30, 2015, must be billed using ICD-9 codes. Professional and outpatient claims with a date of service on or after October 1, 2015, must be billed using ICD-10 codes.

Facility/Institutional inpatient claims with a date of discharge on or before September 30, 2015, must be billed with ICD-9 codes. Facility/Institutional inpatient claims with a date of discharge on or after October 1, 2015, must be billed with ICD-10 codes.

ICD - 9 Diagnosis Code Number(s)
N/A

ICD -10 Diagnosis Code Number(s)

Due to the wide range of applicable diagnosis codes, an inclusive list is not presented.

HCPCS Level II Code Number(s)

MEDICALLY NECESSARY

OSTEOGENESIS STIMULATOR FOR NON-INVASIVE DEVICES
E0747 Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748 Osteogenesis stimulator, electrical, noninvasive, spinal applications

OSTEOGENESIS STIMULATOR FOR INVASIVE DEVICES
E0749 Osteogenesis stimulator, electrical, surgically implanted

ULTRASOUND STIMULATOR FOR NON-INVASIVE DEVICES
E0760 Osteogenesis stimulator, low intensity ultrasound, noninvasive
EXPERIMENTAL/INVESTIGATIONAL

THE FOLLOWING CODE IS USED TO REPRESENT SEMI-INVASIVE ELECTRICAL BONE GROWTH STIMULATOR:
E1399 Durable medical equipment, miscellaneous

Revenue Code Number(s)
N/A

Cross References

Policy: 00.01.25ac: PPO Network Rules for Provision of Specialty Services for Durable Medical Equipment and Laboratory, Radiology, and Physical Medicine and Rehabilitation Services

Policy: 05.00.21p: Durable Medical Equipment (DME)

Policy: 05.00.44g: Repair and Replacement of Durable Medical Equipment (DME)

Version Effective Date: 10/07/2015