Policy: MP029
Section: Medical Benefit Policy
Subject: Bone Growth Stimulator

I. Policy: Bone Growth Stimulator

II. Purpose/Objective:
To provide a policy of coverage regarding Bone Growth Stimulator

III. Responsibility:
A. Medical Directors
B. Medical Management Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than the department requiring/authoring the policy.
3. Devised – the date the policy was implemented.
4. Revised – the date of every revision to the policy, including typographical and grammatical changes.
5. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis, and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards of good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient.

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:
(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.
(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.
(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age.

**ALL Durable Medical Equipment** provided for home use requires advanced determination of coverage. Devices furnished at inpatient or outpatient centers are **NOT SEPARATELY REIMBURSABLE**.

**DESCRIPTION:**
Bone growth stimulation is a medical procedure to aid in bone healing. Both internal (invasive) and external (non-invasive) devices are available. Non-invasive stimulators use either pulsed electromagnetic fields, capacitative coupling, or ultrasound. Electrical stimulators generate a weak electric current through the fracture site. Ultrasonic stimulators emit low intensity, pulsed ultrasonic energy. Invasive stimulation requires surgical implantation of a direct current generator while an electrode is implanted within the fragments of bone graft at the fusion site. The power source is removed in a second surgical procedure when stimulation is completed. The following are considered to be long bones: clavicle, humerus, radius, ulna, femur, tibia, fibula, metatarsals, and metacarpals.

**INDICATIONS:**

**A** Electrical bone growth stimulation (invasive or non-invasive) is considered medically necessary for **ANY** of the following indications:

1. Fracture non-union of long bones
   a) Location in the appendicular skeleton; **AND**
   b) At least 3 months have elapsed since the date of fracture; **AND**
   c) A minimum of 2 sets of radiographs obtained prior to initiation of the osteogenesis stimulator, separated by a minimum of 90 days, including multiple views of the fracture site and a written interpretation by a physician that documents that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; **AND**
   d) The fracture gap is 1cm or less; **AND**
   e) The fracture has been adequately immobilized, and compliance with non-weight bearing activity has been achieved.

2. As an adjunct to spinal fusion surgery when **ANY** of the following are met
   a) Failed spinal fusion is defined as having not healed as evidenced by a minimum of 9 months has elapsed since the last surgery and a minimum of 2 sets of radiographs obtained prior to initiation of the osteogenesis stimulator, separated by a minimum of 90 days, including multiple views of the fracture site and a written interpretation by a physician that documents that there has been no clinically significant evidence of fracture healing between the two sets of radiographs; **OR**
   b) Risk of failed fusion as evidenced by **ANY** of the following indications:
      (1) Grade III or worse spondylolisthesis; **OR**
      (2) Multiple level fusion (involves 3 or more vertebrae); **OR**
      (3) Documented history of previously failed fusion at the same site; **OR**
      (4) Presence of **ANY** risk factors for non-healing such as:
         (a) Smoking;
         (b) Diabetes;
         (c) Renal Disease;
         (d) Long-term steroid treatment;
         (e) Poor nutritional status;
         (f) Other metabolic disease where bone healing is likely to be compromised;

3. Failed fusion of a joint, other than the spine, in which a minimum of 9 months has elapsed since the last surgery; **OR**

4. Congenital pseudoarthrosis

**B** Low-intensity non-invasive ultrasound stimulation is considered medically necessary for **ANY** of the following indications:
1. For the treatment of fresh, closed fractures with closed reduction in skeletally mature adults for ANY of the following acute fracture indications:
   a) Fresh (i.e. less than 7 days), closed, grade I open, tibial diaphyseal fractures; OR
   b) Fresh (i.e. less than 7 days), closed fractures of the distal radius (Colles’ fracture)
   c) Fresh (i.e. less than 7 days), closed fractures at high risk for non-union due to position and poor vascular supply including but not limited to: carpal navicular/scaphoid fractures, Jones/5th metatarsal fracture

2. For the treatment of non-union fractures when ALL of the following criteria are met:
   a) At least 3 months have elapsed since the date of fracture; AND
   b) A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenesis stimulator, separated by a minimum of 90 days, each including multiple view of the fracture site, and 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
   c) The fracture is not of the skull or vertebrae; AND
   d) The fracture is not tumor related AND
   e) The fracture has been adequately immobilized, and compliance with non-weight bearing activity has been achieved.

NOTE: Where applicable, coverage for non-invasive bone growth stimulator will be subject to the limitations of the applicable benefit document. Coverage for invasive electrical bone growth stimulator is considered a medical benefit and is NOT subject to limitations of the Durable Medical Equipment benefit.

EXCLUSIONS: (Apply to both invasive and non-invasive stimulators)
- Non-union fractures of short bones
- Treatment of delayed union (a decelerating fracture healing process, as identified by serial x-rays)
- Fresh fractures (other than when using ultrasound bone stimulation for the tibia or radius)
- Phalanx fractures
- Sesamoid fractures without evidence of nonunion
- Avulsion fractures
- Osteochondral lesions
- Stress fractures without evidence of nonunion and in the absence of a minimum of 90 days of non-surgical management including continued non weight-bearing
- Displaced fractures
- Synovial pseudoarthrosis
- The bone gap is either greater than 1 cm or greater than one-half the diameter of the bone
- Treatment of Charcot foot, avascular necrosis of the hip and fractures of the scapula or pelvis
- To speed recovery based on convenience or athletic status and non-surgical management has not been in place for 90 days included continued non-weight bearing

CODING ASSOCIATED WITH: Bone Growth Stimulator
The following codes are included below for informational purposes and may not be all inclusive. Inclusion of a procedure or device code(s) does not constitute or imply coverage nor does it imply or guarantee provider reimbursement. Coverage is determined by the member specific benefit plan document and any applicable laws regarding coverage of specific services. Please note that per Medicare coverage rules, only specific CPT/HCPCS Codes may be covered for the Medicare Business Segment. Please consult the CMS website at www.cms.gov or the local Medicare Administrative Carrier (MAC) for more information on Medicare coverage and coding requirements.

Coding associated with: Electrical Stimulation

CPT Codes
20974  Electrical stimulation to aid bone healing; noninvasive
20975  invasive
20979  low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS Codes
E0747  Osteogenesis stimulator, electrical, noninvasive, other than spinal applications
E0748  Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749  Osteogenesis stimulator, electrical (surgically implanted)*
E0760  Osteogenesis stimulator, low intensity ultrasound, non-invasive

* Requires prior authorization by a Plan Medical Director

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy. For Medicare, applicable LCD’s and NCD’s will supersede this policy. For PA Medicaid Business segment, this policy applies as written.

REFERENCES:


DMERCA LCD L11501 Osteogenesis Stimulators


CMS, National Coverage Decision, Ultrasound Stimulation for Nonunion Fracture Healing (CAG-00022N)


CMS, National Coverage Decision, Ultrasound Stimulation for Nonunion Fracture Healing (CAG-00022R)


This policy will be revised as necessary and reviewed no less than annually.

Devised: 9/26/01

Revised: 2/04 (indications, criteria, coding) 10/04 (coverage change for invasive and US stimulation); 5/05 (CMS criteria change); 5/06 (Indications/Criteria/coding/format); 5/07 (criteria); 5/08 (criteria), 10/14 (criteria); 10/16 (criteria, removed P/A), 9/17 (clarified exclusions)

Reviewed: 9/02, 9/09, 10/10, 10/11, 10/12, 10/13, 10/15, 9/18