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.

PRIOR AUTHORIZATION:
Prior authorization by a Health Plan Medical Director or Designee is required for any invasive and non invasive indication.
CRITERIA FOR COVERAGE:
A Electrical bone growth stimulation (invasive or non-invasive) may be 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;
   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) 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 may be 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 1 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.

**ADDITIONAL INFORMATION:**

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

**EXCLUSIONS:**
- 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
- Avulsion fractures
- Osteochondral lesions
- Stress fractures 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

**Definitions**

*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.

*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 medial treatment practiced by the general medical
community;
d. not primarily for the convenience of the Member, or the Member’s Health Care Provider; and
e. 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:
a. the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or
disability.
b. 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.
c. 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.

Responsibility:
A. Medical Directors
B. Medical Management Department
C. Pharmacy Department (Medical Benefit Pharmaceutical Policies only)

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.

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)


The use of specific product names is illustrative only. It is not to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.
DOCUMENT HISTORY:

Medical Management Committee Approval Date: 9/26/01
Medical Management Administrative Committee Approval Date: 2/27/04 (electronic vote)
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)
Reviewed: 9/02, 9/09, 10/10, 10/11, 10/12, 10/13, 10/15