Clinical Policy: Osteogenic Stimulation

Reference Number: LA.CP.MP.194
Date of Last Revision: 02/22

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Electrical osteogenic stimulation can be performed invasively or non-invasively. Invasive osteogenic stimulators provide electrical stimulation directly to the non-healing fracture or bone fusion site through percutaneously placed cathodes or by implantation of a coiled cathode wire. Noninvasive osteogenic stimulators deliver an electrical current to the fracture site via capacitive coupling, pulsed electromagnetic field (PEMF), or combined magnetic field technology through treatment coils that are placed externally around the fracture. An ultrasonic osteogenic stimulator is a noninvasive device that emits low intensity, pulsed ultrasound. The device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing.

This policy outlines the medical necessity criteria for electrical and ultrasonic osteogenic stimulators to enhance the bone healing process.

Policy/Criteria

I. It is the policy of Louisiana Healthcare Connections that *noninvasive osteogenesis stimulators* are **medically necessary** when any of the following apply:

A. Nonunion 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 and all of the following:
   1. The bone is not infected;
   2. The two portions of the bone involved in the non-union are separated by less than one centimeter (cm);
   3. The bone is stable at both ends by means of a cast or fixation;
   4. 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;

B. Failed fusion of a joint, other than the spine, in which a minimum of six months has elapsed since the last surgery;

C. Congenital pseudoarthosis;

D. As an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis due to previously failed fusion surgery or for those undergoing a multilevel spinal fusion (involving three or more vertebrae);

E. Risk of delayed or non-union of fractures due to the following conditions or comorbidities (list may not be all inclusive):
   1. Alcoholism;
   2. Chemotherapy;
   3. Diabetes;

4. Obesity;
5. Osteoporosis;
6. Renal disease;
7. Smoking habit;
8. Steroid use.

II. It is the policy of Louisiana Healthcare Connections that *invasive osteogenesis stimulators* are **medically necessary** when any of the following apply:

A. Nonunion of long bone fracture and all of the following:
   1. The bone is not infected;
   2. The two portions of the bone involved in the non-union are separated by less than one cm;
   3. The bone is stable at both ends by means of a cast or fixation;
   4. Serial radiographs (X-rays) 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;

B. Failed spinal fusion in which a minimum of nine months has elapsed since the last surgery and/or as an adjunct to spinal fusion surgery for patients at high risk of pseudoarthrosis;

C. Following a multilevel spinal fusion (involving three or more vertebrae);

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

E. Risk of delayed or non-union of fractures due to the following conditions or comorbidities (list may not be all inclusive):
   1. Alcoholism;
   2. Chemotherapy;
   3. Diabetes;
   4. Obesity;
   5. Osteoporosis;
   6. Renal disease;
   7. Smoking habit;
   8. Steroid use.

III. It is the policy of Louisiana Healthcare Connections that *ultrasonic osteogenesis stimulators* are **medically necessary** when any of the following apply:

A. 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 and at least one of the following risk factors exist:
   1. Fracture associated with extensive soft tissue or vascular damage;
   2. Fresh (seven days or less in duration), closed or grade I open, short oblique or short spiral tibial diaphyseal fractures treated with closed reduction and cast immobilization in skeletally mature patients;
   3. Fresh, closed fractures of the distal radius (Colles' fracture) treated with closed reduction and cast immobilization in skeletally mature patients;
   4. Fresh Jones fracture (5th metatarsal);

5. Fresh fractures of the scaphoid;
6. Nonunion of bones other than the skull or vertebrae in skeletally mature patients, and excluding those that are related to malignancy when the following are met:
   a. Documented by a minimum of two sets of radiographs obtained prior to starting treatment, separated by a minimum of 90 days;
   b. The two portions of the bone involved in the non-union are separated by less than one cm;
   c. The patient has failed more than one surgery and other medical therapies (e.g. immobilization and non-weight bearing status);

B. Risk of delayed or nonunion of any fresh, closed fractures due to the following conditions or comorbidities (list may not be all inclusive):
1. Alcoholism;
2. Chemotherapy;
3. Diabetes;
4. Obesity;
5. Osteoporosis;
6. Renal disease;
7. Smoking habit;
8. Steroid use.

IV. It is the policy of Louisiana Healthcare Connections that *ultrasonic osteogenesis stimulators* are **not medically necessary** for the following indications:
A. Used with other noninvasive osteogenic stimulators;
B. Avascular necrosis of the femoral head;
C. Stress fractures;
D. Fractures in which the gap exceeds one cm;
E. Fresh fractures in locations other than distal radius, tibial diaphysis, 5th metatarsal (Jones fracture only) or scaphoid;
F. Fresh tibial diaphyseal or tibial and fibular fractures treated with closed reduction and intramedullary nailing and no risk factors for poor or prolonged healing;
G. Preoperative use for fractures that require surgical intervention, or internal or external fixation (i.e., use of ultrasonic bone growth stimulators for fractures in the preoperative period would not be medically necessary);
H. Tibial stress fractures.

V. It is the policy of Lousiana Healthcare Connections that osteogenic devices are **not medically necessary** for nonunion fractures of the skull, vertebrae, or those that are tumor-related.

Background

Of the estimated 5.6 million fractures that occur annually in the United States, approximately five to 10 percent 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 include 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 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 seven days post fracture. There is insufficient evidence to conclude that US therapy is useful for any other type of fresh fracture. While no 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 of greater than nine months and in those with delayed unions with a fracture age of three to nine 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 eighty four to one hundred percent, respectively. US therapy promotes healing in complicated cases, such as those with metal implants or with fractures greater than three years old. No 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.

Coding Implications
This clinical policy references Current Procedural Terminology (CPT®). CPT® is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2020, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only and may not support medical necessity. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT®* Codes	Description
20974	Electrical stimulation to aid bone healing; non invasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

CPT®* Codes	Description
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

HCPCS ®* Codes	Description
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
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Converted Corporate to local policy	2/22	

References

1. National coverage determination: osteogenic stimulators (150.2). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/search.asp. Published April 27, 2005. Accessed August 16, 2021.
2. Low intensity ultrasound treatment for acceleration of bone fracture healing – Exogen™ bone growth stimulator. Exogen. MSAC application 1030. http://www.msac.gov.au/internet/msac/publishing.nsf/Content/74AD57FC3C7B2372CA25801000123B50/$File/1030-Exogen-bone-growth-stimulator-Assessment-Report.pdf. Published November 2001. Accessed August 18, 2021.
3. Akai M, Hayashi K. Effect of electrical stimulation on musculoskeletal systems; a meta-analysis of controlled clinical trials. *Bioelectromagnetics*. 2002;23(2):132-143. doi:10.1002/bem.106
4. Akai M, Kawashima N, Kimura T, Hayashi K. Electrical stimulation as an adjunct to spinal fusion: a meta-analysis of controlled clinical trials. *Bioelectromagnetics*. 2002;23(7):496-504. doi:10.1002/bem.10041
5. Banken R. Low-intensity ultrasound (Exogen) for the treatment of fractures. AETMIS 03-05. Montreal, QC: Agence d'Evaluation des Technologies et des Modes d'Intervention en Sante (AETMIS); 2004.
6. Bassett CA, Schink-Ascani M. Long-term pulsed electromagnetic field (PEMF) results in congenital pseudarthrosis. *Calcif Tissue Int*. 1991;49(3):216-220. doi:10.1007/BF02556121
7. Busse JW, Bhandari M, Kulkarni AV, Tunks E. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: A meta-analysis. *Can Med Assoc J*. 2002;166(4):437-441.
8. Garland DE, Moses B, Salyer W. Long-term follow-up of fracture nonunions treated with PEMFs. *Contemp Orthoped*. 1991;22(3):295-302.
9. Hadjiargyrou M, McLeod K, Ryaby JP, et al. Enhancement of fracture healing by low intensity ultrasound. *Clin Orthop Relat Res.* 1998;(355 Suppl):S216-S229. doi:10.1097/00003086-199810001-00022

10. Heckman JD, Ryaby JP, McCabe J, et al. Acceleration of tibial fracture-healing by non-invasive, low-intensity pulsed ultrasound. *J Bone Joint Surg Am*. 1994;76(1):26-34. doi:10.2106/00004623-199401000-00004
11. Holmes GB. Treatment of delayed unions and nonunions of the proximal fifth metatarsal with pulsed electromagnetic fields. *Foot Ankle Int*. 1994;15(10):552-556. doi:10.1177/107110079401501006
12. Kahanovitz N. Spine update. The use of adjunctive electrical stimulation to enhance the healing of spine fusions. *Spine (Phila Pa 1976)*. 1996;21(21):2523-2525. doi:10.1097/00007632-199611010-00026
13. Kane WJ. Direct current electrical bone growth stimulation for spinal fusion. *Spine (Phila Pa 1976)*. 1988;13(3):363-365. doi:10.1097/00007632-198803000-00026
14. Kristiansen TK, Ryaby JP, McCabe J, et al. Accelerated healing of distal radial fractures with the use of specific, low-intensity ultrasound. A multicenter, prospective, randomized, double-blind, placebo-controlled study. *J Bone Joint Surg Am*. 1997;79(7):961-973. doi:10.2106/00004623-199707000-00002
15. Mayr E, Frankel V, Rüter A. Ultrasound -- an alternative healing method for nonunions? *Arch Orthop Trauma Surg*. 2000;120(1-2):1-8. doi:10.1007/pl00021234
16. Mayr E, Wagner S, Ecker M, Rüter A. Die Ultraschalltherapie bei Pseudarthrosen. 3 Fallbeschreibungen [Ultrasound therapy for nonunions. Three case reports]. *Unfallchirurg*. 1999;102(3):191-196. doi:10.1007/s001130050392
17. Mooney V. A randomized double-blind prospective study of the efficacy of pulsed electromagnetic fields for interbody lumbar fusions. *Spine (Phila Pa 1976)*. 1990;15(7):708-712. doi:10.1097/00007632-199007000-00016
18. Griffin XL, Costa ML, Parsons N, Smith N. Electromagnetic field stimulation for treating delayed union or non-union of long bone fractures in adults. *Cochrane Database Syst Rev*. 2011;(4):CD008471. Published 2011 Apr 13. doi:10.1002/14651858.CD008471.pub2
19. Ricardo M. The effect of ultrasound on the healing of muscle-pediculated bone graft in scaphoid non-union. *Int Orthop*. 2006;30(2):123-127. doi: 10.1007/s00264-005-0034-2
20. Rue JP, Armstrong DW 3rd, Frassica FJ, et al. The effect of pulsed ultrasound in the treatment of tibial stress fractures. *Orthopedics*. 2004;27(11):1192-1195. doi:10.3928/0147-7447-20041101-18
21. Schoelles K, Snyder D, Kaczmarek J, et al. *The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion Fractures*. Rockville (MD): Agency for Healthcare Research and Quality (US); September 21, 2005.
22. Scott G, King JB. A prospective, double-blind trial of electrical capacitive coupling in the treatment of non-union of long bones. *J Bone Joint Surg Am*. 1994;76(6):820-826. doi:10.2106/00004623-199406000-00005
23. Tejano NA, Puno R, Ignacio JM. The use of implantable direct current stimulation in multilevel spinal fusion without instrumentation. *Spine (Phila Pa 1976)*. 1996;21(16):1904-1908. doi:10.1097/00007632-199608150-00015
24. Wang JC, Le AW, Tsukuda RK. A new technique for Charcot's foot reconstruction. *J Am Podiatr Med Assoc*. 2002;92(8):429-436. doi:10.7547/87507315-92-8-429
25. Warden SJ, Bennell KL, McMeeken JM, et al. Acceleration of fresh fracture repair using the sonic accelerated fracture healing system (SAFHS): A review. *Calcif Tissue Int*. 2000;66(2):157-163. doi:10.1007/s002230010031

26. Zura RD, Sasser B, Sabesan V, et al. A survey of orthopaedic traumatologists concerning the use of bone growth stimulators. *J Surg Orthop Adv*. 2007;16(1):1-4.
27. Aleem IS, Aleem I, Evaniew N, et al. Efficacy of electrical stimulators for bone healing: a meta-analysis of randomized sham-controlled trials. *Sci Rep*. 2016;6:31724. doi: 10.1038/srep31724
28. Gan JC, Fredericks DC, Glazer PA. Direct current and capacitive coupling electrical stimulation upregulates osteopromotive factors for spinal fusions. Spine. 2005;15.
29. Kuzyk PRT, Schemitsch EH. The science of electrical stimularion therapy for fracture healing. *Indian J Orthop*. 2009;43(2):127–131. doi: 10.4103/0019-5413.50846

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of member/enrollee. This clinical policy is not intended to recommend treatment for member/enrollee. Member/enrollee should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom LHCC has no control or right of control. Providers are not agents or employees of LHCC.