Clinical Policy: Osteogenic Stimulation

Reference Number: CP.MP.194 Coding Implications
Last Review Date: 09/20 Revision Log

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

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

Electrical 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.

Policy/Criteria
I. It is the policy of health plans affiliated with Centene Corporation® that *noninvasive osteogenesis stimulators (non-spinal electrical osteogenesis stimulators)* are **medically necessary** when any of the following criteria apply:
   A. Non-union 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 non-infected;
      2. The two portions of the bone involved in the non-union are separated by less than 1 centimeter (cm);
      3. The bone is stable at both ends by means of a cast or fixation;
      4. When 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 where 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 fusion at more than one level;
   E. Risk of delayed or non-union of fractures due to the following 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 health plans affiliated with Centene Corporation® that *invasive osterogenesis stimulators (spinal electrical osteogenesis stimulators)* are **medically necessary** when any of the following criteria apply:

A. Non-union of long bone fracture and all of the following:
   1. The bone is non-infected;
   2. The two portions of the bone involved in the non-union are separated by less than 1 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 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 9 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;

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 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 health plans affiliated with Centene Corporation® that *ultrasonic osteogenesis stimulators* are **medically necessary** when any of the following criteria apply:

A. 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 and at least one of the following risk factors exist:
   1. Fractures associated with extensive soft tissue or vascular damage;
   2. Fresh (7 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 criteria 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 patient has failed ≥ 1 surgery and other medical therapies;

B. Risk of delayed or non-union of ANY fresh, closed fractures due to the following 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 health plans affiliated with Centene Corporation® that *ultrasonic osteogenesis stimulators* are **not medically necessary** for the following indications:
A. If used with other noninvasive osteogenic stimulators;
B. Avascular necrosis of the femoral head;
C. Stress fractures;
D. Fractures in which the gap exceeds 1 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 BGS for fractures in the preoperative period would not be covered);
H. Tibial stress fractures.

V. It is the policy of health plans affiliated with Centene Corporation® 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 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 post fracture. 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.

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 2019, 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. 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)
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

Reviews, Revisions, and Approvals	Date	Approval Date
Original approval date	8/2/2011	8/2/2011
New template design approved by MPC.	12/1/2011	12/1/2011
Retired by MPC; covered by InterQual.	7/5/2012	7/5/2012
Approved by MPC and now used for coverage determinations (see Position Statement).	9/4/2014	9/4/2014
Approved by MPC. No changes.	6/5/2015	6/5/2015
Approved by MPC. No changes.	9/15/2016	9/15/2016
Approved by MPC. No changes.	12/7/2017	12/7/2017
Approved by MPC. No changes.	11/1/2018	11/1/2018
Approved by MPC. No changes.	11/7/2019	11/7/2019
Transferred to CNC template; previously named HS-019. Replaced "members" with "members/enrollees" in all instances.	09/20	09/20

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 2005. Accessed September 4, 2020.
2. Decision memo for ultrasound stimulation for nonunion fracture healing (CAG-00022R). Centers for Medicare and Medicaid Services Web site. http://www.cms.hhs.gov/mcd/viewdecisionmemo.asp?id=135. Published April 27, 2005. Accessed September 4, 2020.
3. Medical Services Advisory Committee (MSAC). Low intensity ultrasound treatment for acceleration of bone fracture healing - Exogen bone growth stimulator. Canberra, Australia: MSAC; 2001.
4. U.S. Food and Drug Administration (FDA). FDA approves device to speed healing of fractures. FDA Talk Paper. Rockville, MD: FDA; October 12, 1994.
5. Hayes health technology Assessment. Ultrasound bone growth stimulation. Published September 3, 2015 (annual review October 25, 2019). Accessed September 4, 2020.
6. Akai M, Hayashi K. Effect of electrical stimulation on musculoskeletal systems: A meta-analysis of controlled clinical trials. Bioelectromagnetics. 2002;23(2):132-143.
7. 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.
8. Albert SF, Wong E. Electrical stimulation of bone repair. Clinics Pod Med Surg. 1991;8(4):923-935.

9. Alberta Heritage Foundation for Medical Research (AHFMR). Ultrasound treatment - nonunion fractures. Edmonton, AB: AHFMR; 1999.
10. 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.
11. Basset C, Schink-Ascani M. Long-term pulsed electromagnetic field (PEMF) results in congenital pseudarthrosis. Calcif Tissue Int. 1991;49(3):216-220.
12. Brighton CT. Use of constant direct current in the treatment of nonunion. American Academy of Orthopedic Surgeons, Instructional Course Lectures. Park Ridge, IL: AAOS; 1981.
13. Brown E. Noninvasive electrical stimulation for fracture nonunions. Diagnostic and Therapeutic Technology Assessment, American Medical Association. Chicago, IL: American Medical Association; February 1, 1989.
14. Busse JW, Bhandari M, Kulkarni AV, Schünemann HJ. Therapeutic ultrasound for fracture healing in adults (Protocol for Cochrane Review). Cochrane Database Syst Rev. 2005;(3):CD005464.
15. 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.
16. Cook SD, Ryaby JP, McCabe J, et al. Acceleration of tibia and distal radius fracture healing in patients who smoke. Clin Orthop. 1997;337:198-207.
17. Duarte L, Choffie M. Low intensity pulsed ultrasound and effects on ununited fractures. Paper presented at the Orthopedic Health Conference, University Hospital, University of Sao Paulo, Brazil, June 1994.
18. Exogen. Summary of safety and efficacy data. Exogen 2000 or Sonic Accelerated Fracture Healing System. PMA Number:900009, Suppl. 6. Piscataway, NJ: Exogen; 2000.
19. Garland DE, Moses B, Salyer W. Long-term follow-up of fracture nonunions treated with PEMFs. Contemp Orthoped. 1991;22(3):295-302.
20. Gudas CJ, Cann JE. Nonunions and related disorders. Clinics Podc Med Surg. 1991;8(2):321-339.
21. Hadjiargyrou M, McLeod K, Ryaby JP, et al. Enhancement of fracture healing by low intensity ultrasound. Clin Orthop. 1998;355 Suppl:S216-S229.
22. 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.
23. 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.
24. Kahanovitz N. Spine update. The use of adjunctive electrical stimulation to enhance the healing of spine fusions. Spine. 1996;21(21):2523-2525.
25. Kane WJ. Direct current electrical bone growth stimulation for spinal fusion. Spine. 1988;13:163-165.
26. 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.
27. Mayr E, Frankel V, Rüter A. Ultrasound -- an alternative healing method for nonunions? Orthop Trauma Surg. 2000;120:1-8.

28. Mayr E, Wagner S, Ecker M, et al. Ultrasound therapy for nonunions (pseudarthrosis): 3 case reports. Unfallchirurg. 1999;123:191-196.
29. Mayr E, Wagner S, Rüter A. Treatment of nonunions by means of low-intensity ultrasound. Unfallchirurg. 1997;121:958-962.
30. Mooney V. A randomized double blind prospective study of the efficacy of pulsed electromagnetic fields for interbody fusions. Spine. 1990;15:8-12.
31. Punt B, den Hoed P, Stijnen T. Electromagnetic field stimulation for the treatment of delayed union or non-union of long bones (Protocol for Cochrane Review). Cochrane Database Syst Rev. 2004;(4):CD004960.
32. 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.
33. 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.
34. Schoelles K, Snyder D, Kaczmarek J, et al. The role of bone growth stimulating devices and orthobiologics in healing nonunion fractures. Technology Assessment. Prepared by the ECRI Evidence-Based Practice Center for the Agency for Healthcare Research and Quality (AHRQ). Rockville, MD: AHRQ; September 21, 2005.
35. 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. 1994;76A(6):820-826.
36. Tejano NA, Puno R, Ignacio JM. The use of implantable direct current stimulation in multilevel spinal fusion without instrumentation. Spine. 1996;21(16):1904-1908.
37. Wang JC, Le AW, Tsukuda RK. A new technique for Charcot's foot reconstruction. J Am Podiatr Med Assoc. 2002;92(8):429-436.
38. 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;66:157-163.
39. 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.
40. Belinda Robinson, American Academy of Orthopedic Surgeons, Rosemount, IL, personal communication, December 1995.

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. The Health Plan 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. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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 Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. 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. The Health Plan 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 members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees 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 the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members/enrollees and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members/enrollees and their representatives agree to be bound by such terms and conditions by providing services to members/enrollees and/or submitting claims for payment for such services.

Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.