Clinical Policy: Osteogenic Stimulation

Reference Number: NC.CP.MP.194
Date of Last Revision: ~~09/2024~~

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 (CC), pulsed electromagnetic field (PEMF), or combined magnetic field technology (CMFT) through treatment coils that are placed externally around the fracture.[29] 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.[1]

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 health plans affiliated with Centene Corporation® that *noninvasive electrical 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 appropriate fracture care and immobilization;
   4. Serial imaging have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the noninvasive electrical bone growth stimulator. Serial imaging must include a minimum of two sets of images , 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 pseudoarthrosis;

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) or Grade III spondylolisthesis;

E. Risk of delayed or non-union of fractures due to certain conditions including but not limited to alcoholism, chemotherapy, diabetes, nutritional deficiency, obesity, osteoporosis, renal disease, severe anemia, tobacco or steroid use ~~the following conditions or comorbidities (list may not be all inclusive):~~

~~1. Alcoholism;~~
~~2. Chemotherapy;~~
~~3. Diabetes;~~
~~4. Nutritional Deficiency~~
~~5. Obesity;~~
~~6. Osteoporosis;~~
~~7. Renal disease;~~
~~8. Tobacco use;~~
~~9. Severe Anemia~~
~~10. Steroid use.~~

II. It is the policy of health plans affiliated with Centene Corporation that *invasive electrical 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 appropriate fracture care and immobilization;
   4. Serial imaging have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the invasive bone growth stimulator. Serial imaging must include a minimum of two sets of images , each including multiple views of the fracture site, separated by a minimum of 90 days;

B. 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) or Grade III spondylolisthesis;

C. Risk of delayed or non-union of fractures due certain conditions including but not limited to alcoholism, chemotherapy, diabetes, nutritional deficiency, obesity, osteoporosis, renal disease, severe anemia, tobacco or steroid use~~to the following conditions or comorbidities (list may not be all inclusive):~~
   ~~1. Alcoholism;~~
   ~~2. Chemotherapy;~~
   ~~3. Diabetes;~~
   ~~4. Nutritional Deficiency~~
   ~~5. Obesity;~~
   ~~6. Osteoporosis;~~
   ~~7. Renal disease;~~
   ~~8. Tobacco use;~~
   ~~9. Severe Anemia~~
   ~~10. 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 apply:

A. Used as an adjunct to conventional management (i.e., closed reduction and cast immobilization; fixation; custom bracing; or orthosis;) 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; fixation; custom bracing; or orthosis in skeletally mature patients;
3. Fresh, closed fractures of the distal radius (Colles' fracture) treated with closed reduction and cast immobilization; fixation; custom bracing; or orthosis 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 imaging 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.~~

B. 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 imaging 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.

~~B.~~C. Risk of delayed or nonunion of any fresh, closed fractures due to certain conditions including but not limited to alcoholism, chemotherapy, diabetes, nutritional deficiency, obesity, osteoporosis, renal disease, severe anemia, tobacco or steroid use~~the following conditions or comorbidities (list may not be all inclusive):~~
   1. ~~Alcoholism;~~
   2. ~~Chemotherapy;~~
   3. ~~Diabetes;~~
   4. ~~Nutritional Deficiency;~~
   5. ~~Obesity;~~
   6. ~~Osteoporosis;~~
   7. ~~Renal disease;~~
   8. ~~Tobacco use;~~
   9. ~~Severe Anemia;~~
   10. ~~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. 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, scaphoid, or ~~5th metatarsal (Jones fracture only) or scaphoid~~or Jones fracture of the 5th metatarsal ;

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 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 7.9 million fractures that occur annually in the United States, approximately five to 10 percent will demonstrate signs of delayed or impaired healing.[3] 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 much space 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 (LIPUS) therapy.[4,5]

Ultrasonic (US) Osteogenic Stimulation

In LIPUS technology, 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, LIPUS causes biochemical changes at the cellular level that promote and accelerate bone formation, and thus, fracture healing. LIPUS 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 LIPUS device, which is prescribed by a physician, at home for 20 minutes once daily until healing occurs.[5,6,7]

LIPUS therapy safely and effectively enhances the fracture healing process at the cellular, radiological, and clinical level. At-home use of the LIPUS 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 LIPUS therapy is useful for any other type of fresh fracture.[5,8] LIPUS improved quality of life when compared to placebo for treatment of fresh fractures, in addition to providing 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.[5,6]

LIPUS 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.[7,9] 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 85 to 100%, respectively. LIPUS therapy promotes healing in complicated cases, such as those with metal implants or with fractures greater than three years old.[10]

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 (CC), pulsed electromagnetic field (PEMF), or combined electromagnetic field (CEMF) technology.[1,2,11]

Available evidence from an FDA literary review confirms expected benefits of PEMF and CEMF devices; however, variation in methodology, such as differences in devices used, anatomic location, treatment waveform and frequency, and patient population, likely account for the effectiveness range of 32.8% to 97.4%. Noninvasive electrical bone growth stimulation, particularly when delivered via PEMF, can stimulate healing of long bone fracture nonunion. A single arm prospective study findings demonstrated a 77.3% fusion rate in the tibia via PEMF. Additional randomized control studies resulted in an 83.6% fusion rate in the treatment group compared to a 68.6% fusion rate in the control group. 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.[11] There is limited evidence to support the effectiveness of electromagnetic bone stimulation to treat atypical or stress fractures that would otherwise require surgery.[4] There is also some evidence to support the efficacy of noninvasive electrical stimulation as an adjunct to surgery for spinal fusion, however, the evidence is less consistent. One retrospective study of spinal fusion rates via PEMF showed a 73.2% fusion rate in the cervical spine at 6 months.[1,11] A preliminary observational study designed to investigate the role of CC to treat vertebral edema in acute vertebral compression fractures demonstrated improvement in symptoms, faster fracture healing and complete resolution of the vertebral edema.[12] A critical analysis of eleven studies using CC notes high level of evidence for its effectiveness for treating nonunion fractures. Although electrical stimulation demonstrates promise in promoting bone healing, better-designed clinical studies are needed for optimal application in clinical practice.[13] A recent small study of 29 patients with confirmed nonunion fractures evaluated union rates and times following CEMF treatment. Findings demonstrated an overall success rate of 84% with an average union time of 6.62 months. Additional studies need to be conducted to confirm efficacy conclusively.[14] In one of the first studies to compare PEMF and CEMF treatment following spinal fusion in a group of 60 patients, CEMF was superior to PEMF, even though, the addition of the bone growth stimulators did not improve fusion outcomes.[15]

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.[2]

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 2022, 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
E0760	Osteogenesis stimulator, low intensity ultrasound, noninvasive

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Original approval date.	8/11	8/11
Approved by MPC. No changes.	11/19	11/19
Transferred to CNC template; previously named HS-019. Replaced "members" with "members/enrollees" in all instances.	09/20	09/20
Annual review. Removed "(non-spinal electrical osteogenesis stimulators) from policy statement I. Updated criteria I.C. from, "fusion at more than one level," to, "multilevel fusion." Added definition of multilevel spinal fusion as "involving three or more vertebrae" to criteria points I.D. and II.C. Removed "(spinal electrical osteogenesis stimulators)" from policy statement II. Reviewed and updated references. Removed criteria point II.D., "D. Following spinal fusion surgery where there is a history of a previously failed spinal fusion at the same site," as it was duplicative of criteria point II.B. Added code E0760. Changed "review date" in the header to "date of last revision" and date" in the revision log header to "revision date." Minor changes to background with no clinical significance. Reviewed by specialist.	09/21	09/21

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Annual review completed. Added "electrical" to I. and II. Replaced "smoking habit" with "tobacco use" in criteria I.E.7., II.E.7., and III.B.7. Removed criteria point III.6.c. "The patient has failed more than one surgery and other medical therapies (e.g. immobilization and non-weight bearing status)". Background updated and minor rewording with no clinical significance. References reviewed and updated. Specialist reviewed.	09/22	09/22
Annual review completed. Background and references reviewed and updated.	08/23	08/23
CCH specific policy developed. Added "custom bracing; or orthosis" to Criterion I.3, Criterion 1.A.3, II.A.3, III.A, III.A.2, and III.A.3.; Added "Nutritional Deficiency and Severe Anemia to Criterion I.E., II.C, and III.B. Added "or Grade III spondylolisthesis" to criterion I.D.; Removed Criteria II.B, C. and D. and added "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) or Grade III spondylolisthesis" to now Criterion II.B.	11/23	11/23
Annual review. Updated Criteria I.A.3. to state, "appropriate fracture care and immobilization." Updated language in Criteria I.A.4. from radiographs to imaging. Updated Criteria II.A.3. to state, "appropriate fracture care and immobilization." Updated language in Criteria II.A.4. from radiographs to imaging. Updated language in Criteria III.A.6.a. from radiographs to imaging. Background updated with no impact on criteria. References reviewed and updated. Reviewed by external specialist.	09/24	09/24
Annual review. Changed previous criteria III.A.6.a.-b. to new criteria III.B.1.-2. Reformatted criteria under I.E., II.C., new III.C. and IV.E. with no impact on criteria. References reviewed and updated.		

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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.

 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.