Bone Growth Stimulators - Electric

Date of Origin: 01/2007 **Last Review Date: 03/25/2020** **Effective Date: 04/01/2020**

Dates Reviewed: 01/2008, 01/2009, 02/2011, 01/2012, 09/2012, 07/2013, 06/2014, 09/2014, 05/2015, 07/2015, 10/2016, 07/2017, 03/2019, 03/2020

Developed By: Medical Necessity Criteria Committee

I. Description

Bone growth stimulation is a technique of promoting bone growth in difficult to heal fractures. Two types of bone growth stimulators currently exist: electrical and ultrasonic.

An electric bone growth stimulator uses electric current to promote bone healing. Non-invasive, semi-invasive, and invasive methods of electrical bone growth stimulation are available. Non-invasive uses of an external power supply and externally applied coils that produce direct current or pulsed electromagnetic fields to generate a weak electrical current in the underlying tissue. Semi-invasive, also called percutaneous bone growth stimulation uses an external power supply and electrodes that are inserted through the skin and into the bone where the growth is desired. Invasive bone growth stimulators require surgical implantation of a current generator into a subcutaneous or intramuscular space and an electrode that is implanted into the bone fragments at the fusion site. A second surgical procedure is required to remove the power source after treatment is complete.

Definitions:

Fresh Fracture:
A fracture is most commonly defined as "fresh" for 14 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care, i.e., closed reduction and cast immobilization.

Delayed Union:
Delayed union is defined as a fracture that requires more time than usual to heal and usually shows progression over time. It is a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiologic evidence of union, bony continuity or bone reaction at the fracture sit.

Nonunion:
A nonunion is considered to be established when a minimum of nine months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of three months. Signs of nonunion may be present on serial radiographs beginning three months from the initial injury.

Malunion:
A malunion occurs when a fractured bone heals in an abnormal position often occurring as a result of significant trauma.

II. Criteria: CWQI HCS-0008B

*For Ultrasonic Bone Growth Stimulators refer to MCG A-0414

A. Non-invasive electrical bone growth stimulators will be covered to plan limitations when **1** or more of the following criteria are met:
    a. Failed joint fusion following arthrodesis (non-spinal). Failed joint fusion is defined as a joint fusion which has not healed at a minimum of 6 months after arthrodesis, as evidenced by serial x-rays over a course of 3 months
    b. Failed spinal fusion. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 9 months after the original surgery, as evidenced by a set of at least two serial x-rays over a course of 9 months
    c. Congenital pseudoarthroses
    d. Fracture nonunions that meet **all** of the following criteria:
        i. Fracture is in one of the following locations:
            1. Long bone (i.e. the bones of the shoulder girdle, upper and lower extremities)
            2. Scaphoid bone
            3. Navicular bone
        ii. At least 3 months have passed since the date of fracture; and
        iii. Serial radiographs at least 3 months apart have confirmed that no progressive signs of healing have occurred; and
        iv. The fracture gap is ≤1 cm; and
        v. The patient can be adequately immobilized and is likely to comply with non-weight bearing.

B. Invasive or non-invasive electrical bone growth stimulators will be covered to plan limitations for skeletally mature individuals as an adjunct to spinal fusion surgery when one of the following risk factors for failed fusion are present:
    a. One or more previous failed spinal fusions
    b. Grade III or worse spondylolisthesis
    c. Fusion to be performed at more than one level
    d. Patient is currently a smoker
    e. Patient has diabetes
    f. Patient has renal disease
    g. Patient has a history of alcoholism
    h. Patient has significant osteoporosis which has been demonstrated on x-rays

C. Invasive electrical bone growth stimulation will be covered to plan limitations for skeletally mature individuals when used as an adjunct to surgical treatment of non-union of a major long bone fracture.

D. Electrical bone growth stimulation is considered investigational when used in the treatment of the including but not limited to All of following

   a. Fresh fractures
   b. Delayed unions
   c. Avascular necrosis
   d. Stress fractures

III. Information Submitted with the Prior Authorization Request:

1. Chart notes from the treating physician showing documentation of original injury and current medical status
2. Treatment history
3. Serial X-ray reports

IV. CPT or HCPC codes covered:

Codes	Description
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0747	Osteogenesis stimulator; electrical, noninvasive, other than spinal applications
E0748	Osteogenesis stimulator, electrical, noninvasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted

V. Annual Review History

Review Date	Revisions	Effective Date
07/2013	Annual Review: Added table with review date, revisions, and effective date.	07/2013
06/2014	Annual Review: Removed skeletally mature for US bone stim for fresh fractures since used in pediatrics as well.	06/2014
05/2015	Annual Review, updated criteria	05/2015
07/2015	Created separate criteria from U/S- added ICD-9 and ICD-10 codes	05/2015
10/2016	Annual Review: No change	10/26/2016
07/2017	Annual Review: Minor wording changes, updated to new template	07/26/2017
03/2019	Annual Review: Clarified criteria relating to fracture nonunion	04/01/2019
03/2020	Annual Review: No changes	04/01/2020

VII. References

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12. Centers for Medicare & Medicaid Services; Local Coverage Determination (LCD): Noridian Healthcare Solutions, Osteogenesis Stimulators. L33796, Medicare Jurisdiction D, DME MAC; Original Effective Date 10/01/2015; Revision Effective Date 07/01/2016. Physician Advisors

Appendix 1 – Applicable ICD-10 diagnosis codes:

Codes	Description
M43.00	Spondylolysis, site unspecified
M43.10	Spondylolisthesis, site unspecified
Q76/2	Congenital spondylolisthesis
S02.91XK	Unspecified fracture of skull, subsequent encounter for fracture with nonunion
S02.92XK	Unspecified fracture of facial bones, subsequent encounter for fracture with nonunion
S12.000K	Unspecified displaced fracture of first cervical vertebra, subsequent encounter for fracture with nonunion
S12.001K	Unspecified nondisplaced fracture of first cervical vertebra, subsequent encounter for fracture with nonunion

S12.100K	Unspecified displaced fracture of second cervical vertebra, subsequent encounter for fracture with nonunion
S12.101K	Unspecified nondisplaced fracture of second cervical vertebra, subsequent encounter for fracture with nonunion
S12.200K	Unspecified displaced fracture of third cervical vertebra, subsequent encounter for fracture with nonunion
S12.201K	Unspecified nondisplaced fracture of third cervical vertebra, subsequent encounter for fracture with nonunion
S12.300K	Unspecified displaced fracture of fourth cervical vertebra, subsequent encounter for fracture with nonunion
S12.301K	Unspecified nondisplaced fracture of fourth cervical vertebra, subsequent encounter for fracture with nonunion
S12.400K	Unspecified displaced fracture of fifth cervical vertebra, subsequent encounter for fracture with nonunion
S12.401K	Unspecified nondisplaced fracture of fifth cervical vertebra, subsequent encounter for fracture with nonunion
S12.500K	Unspecified displaced fracture of sixth cervical vertebra, subsequent encounter for fracture with nonunion
S12.501K	Unspecified nondisplaced fracture of sixth cervical vertebra, subsequent encounter for fracture with nonunion
S22.9XXK	Fracture of bony thorax, part unspecified, subsequent encounter for fracture with nonunion
S32.9XXK	Fracture of unspecified parts of lumbosacral spine and pelvis, subsequent encounter for fracture with nonunion
S42.009K	Fracture of unspecified part of unspecified clavicle, subsequent encounter for fracture with nonunion
S42.009P	Fracture of unspecified part of unspecified clavicle, subsequent encounter for fracture with malunion
S42.209K	Unspecified fracture of upper end of unspecified humerus, subsequent encounter for fracture with nonunion
S42.209P	Unspecified fracture of upper end of unspecified humerus, subsequent encounter for fracture with malunion
S42.90XK	Fracture of unspecified shoulder girdle, part unspecified, subsequent encounter for fracture with nonunion
S42.90XM	Unspecified fracture of unspecified forearm, subsequent encounter for open fracture type I or II with nonunion
S42.90XN	Unspecified fracture of unspecified femur, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion
S42.90XP	Fracture of unspecified shoulder girdle, part unspecified, subsequent encounter for fracture with malunion
S52.90XP	Unspecified fracture of unspecified forearm, subsequent encounter for closed fracture with malunion
S52.90XQ	Unspecified fracture of unspecified forearm, subsequent encounter for open fracture type I or II with malunion

S52.90XR	Unspecified fracture of unspecified forearm, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with malunion
S62.009A	Unspecified fracture of navicular [scaphoid] bone of unspecified wrist, initial encounter for closed fracture
S62.009B	Unspecified fracture of navicular [scaphoid] bone of unspecified wrist, initial encounter for open fracture
S62.60XP	Unspecified fracture of unspecified wrist and hand, subsequent encounter for fracture with malunion
S72.90XP	Unspecified fracture of unspecified femur, subsequent encounter for open fracture type I or II with malunion
S82.009R	Unspecified fracture of unspecified lower leg, subsequent encounter for closed fracture with malunion
S82.101A	Unspecified fracture of upper end of right tibia, initial encounter for closed fracture
S82.101B	Unspecified fracture of upper end of right tibia, initial encounter for open fracture type I or II
S82.102A	Unspecified fracture of upper end of left tibia, initial encounter for closed fracture
S82.102B	Unspecified fracture of upper end of left tibia, initial encounter for open fracture type I or II
S82.109A	Unspecified fracture of upper end of unspecified tibia, initial encounter for closed fracture
S82.109B	Unspecified fracture of upper end of unspecified tibia, initial encounter for open fracture type I or II
S82.109C	Unspecified fracture of upper end of unspecified tibia, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.201A	Unspecified fracture of shaft of right tibia, initial encounter for closed fracture
S82.201B	Unspecified fracture of shaft of right tibia, initial encounter for open fracture type I or II
S82.201C	Unspecified fracture of shaft of right tibia, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.202A	Unspecified fracture of shaft of left tibia, initial encounter for closed fracture
S82.202B	Unspecified fracture of shaft of left tibia, initial encounter for open fracture type I or II
S82.209A	Unspecified fracture of shaft of unspecified tibia, initial encounter for closed fracture
S82.209B	Unspecified fracture of shaft of unspecified tibia, initial encounter for open fracture type I or II
S82.209C	Unspecified fracture of shaft of unspecified tibia, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.401A	Unspecified fracture of shaft of right fibula, initial encounter for closed fracture
S82.401B	Unspecified fracture of shaft of right fibula, initial encounter for open fracture type I or II
S82.402A	Unspecified fracture of shaft of left fibula, initial encounter for closed fracture
S82.402B	Unspecified fracture of shaft of left fibula, initial encounter for open fracture type I or II
S82.53XA	Displaced fracture of medial malleolus of unspecified tibia, initial encounter for closed fracture
S82.53XB	Displaced fracture of medial malleolus of unspecified tibia, initial encounter for open fracture type I or II

S82.53XC	Displaced fracture of medial malleolus of unspecified tibia, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.56XA	Nondisplaced fracture of medial malleolus of unspecified tibia, initial encounter for closed fracture
S82.56.XB	Nondisplaced fracture of medial malleolus of unspecified tibia, initial encounter for open fracture type I or II
S82.56XC	Nondisplaced fracture of medial malleolus of unspecified tibia, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.63XA	Displaced fracture of lateral malleolus of unspecified fibula, initial encounter for closed fracture
S82.63XB	Displaced fracture of lateral malleolus of unspecified fibula, initial encounter for open fracture type I or II
S82.63XC	Displaced fracture of lateral malleolus of unspecified fibula, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.66XA	Nondisplaced fracture of lateral malleolus of unspecified fibula, initial encounter for closed fracture
S82.66XB	Nondisplaced fracture of lateral malleolus of unspecified fibula, initial encounter for open fracture type I or II
S82.66XC	Nondisplaced fracture of lateral malleolus of unspecified fibula, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.831A	Other fracture of upper and lower end of right fibula, initial encounter for closed fracture
S82.831B	Other fracture of upper and lower end of right fibula, initial encounter for open fracture type I or II
S82.832A	Other fracture of upper and lower end of left fibula, initial encounter for closed fracture
S82.832B	Other fracture of upper and lower end of left fibula, initial encounter for open fracture type I or II
S82.843A	Displaced bimalleolar fracture of unspecified lower leg, initial encounter for closed fracture
S82.843B	Displaced bimalleolar fracture of unspecified lower leg, initial encounter for open fracture type I or II
S82.843C	Displaced bimalleolar fracture of unspecified lower leg, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.846A	Nondisplaced bimalleolar fracture of unspecified lower leg, initial encounter for closed fracture
S82.846B	Nondisplaced bimalleolar fracture of unspecified lower leg, initial encounter for open fracture type I or II
S82.846C	Nondisplaced bimalleolar fracture of unspecified lower leg, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.853A	Displaced trimalleolar fracture of unspecified lower leg, initial encounter for closed fracture
S82.853B	Displaced trimalleolar fracture of unspecified lower leg, initial encounter for open fracture type I or II
S82.853C	Displaced trimalleolar fracture of unspecified lower leg, initial encounter for open fracture type IIIA, IIIB, or IIIC

S82.856A	Nondisplaced trimalleolar fracture of unspecified lower leg, initial encounter for closed fracture
S82.856B	Nondisplaced trimalleolar fracture of unspecified lower leg, initial encounter for open fracture type I or II
S82.856C	Nondisplaced trimalleolar fracture of unspecified lower leg, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.899A	Other fracture of unspecified lower leg, initial encounter for closed fracture
S82.899B	Other fracture of unspecified lower leg, initial encounter for open fracture type I or II
S82.899C	Other fracture of unspecified lower leg, initial encounter for open fracture type IIIA, IIIB, or IIIC
S82.90XK	Unspecified fracture of unspecified lower leg, subsequent encounter for closed fracture with nonunion
S82.90XM	Unspecified fracture of unspecified lower leg, subsequent encounter for open fracture type I or II with nonunion
S82.90XN	Unspecified fracture of unspecified lower leg, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with nonunion
S82.90XP	Unspecified fracture of unspecified lower leg, subsequent encounter for closed fracture with malunion
S82.90XQ	Unspecified fracture of unspecified lower leg, subsequent encounter for open fracture type I or II with malunion
S82.90XR	Unspecified fracture of unspecified lower leg, subsequent encounter for open fracture type IIIA, IIIB, or IIIC with malunion
S92.253A	Displaced fracture of navicular [scaphoid] of unspecified foot, initial encounter for closed fracture
S92.253B	Displaced fracture of navicular [scaphoid] of unspecified foot, initial encounter for open fracture
S92.256A	Nondisplaced fracture of navicular [scaphoid] of unspecified foot, initial encounter for closed fracture
S92.256B	Nondisplaced fracture of navicular [scaphoid] of unspecified foot, initial encounter for open fracture
S92.309A	Fracture of unspecified metatarsal bone(s), unspecified foot, initial encounter for closed fracture
S92.309B	Fracture of unspecified metatarsal bone(s), unspecified foot, initial encounter for open fracture
S92.909K	Unspecified fracture of unspecified foot, subsequent encounter for fracture with nonunion
S92.909P	Unspecified fracture of unspecified foot, subsequent encounter for fracture with malunion
S92.919K	Unspecified fracture of unspecified toe(s), subsequent encounter for fracture with nonunion
S92.919P	Unspecified fracture of unspecified toe(s), subsequent encounter for fracture with malunion

Appendix 1 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD):

Jurisdiction(s): 5, 8	**NCD/LCD Document (s):**
Noridian Local Coverage Determination (LCD) L33796	
https://med.noridianmedicare.com/documents/2230703/7218263/Osteogenesis+Stimulators+LCD+and+PA/47719505-bd98-4b36-893d-010192d53088	

NCD/LCD Document (s):

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC