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Electrical Bone Growth Stimulation of the Appendicular Skeleton Corporate Medical Policy

File Name: Electrical Bone Growth Stimulation of the Appendicular Skeleton
File Code: 7.01.VT07
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Next Review: 07/2024
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Description/Summary

In the appendicular skeleton, electrical stimulation with either implantable electrodes or noninvasive surface stimulators has been investigated to facilitate the healing of fresh fractures, stress fractures, delayed union, nonunion, congenital pseudoarthrosis, and arthrodesis.

Noninvasive Electrical Bone Growth Stimulation
For individuals who have fracture nonunion who receive noninvasive electrical bone growth stimulation, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The U.S. Food and Drug Administration (FDA) has approved noninvasive electrical bone growth stimulation for fracture nonunions and congenital pseudarthrosis in the appendicular skeleton, based largely on studies with patients serving as their controls. There is also evidence from 2 small sham-controlled randomized trials that noninvasive electrical stimulators improve fracture healing for patients with fracture nonunion. There are few nonsurgical options in this population, and the pre-post studies of patients with nonhealing fractures support the efficacy of the treatment. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have delayed fracture union who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. RCTs on the delayed union of fractures were limited by small sample sizes and did not show significant differences in outcomes between study groups. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fresh fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes RCTs and systematic reviews of RCTs. Relevant

outcomes are symptoms, change in disease status, and functional outcomes. A meta-analysis of 5 RCTs found no statistically significant benefit of electrical bone growth stimulation for fresh fractures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have stress fracture(s) who receive noninvasive electrical bone growth stimulation, the evidence includes an RCT. Relevant outcomes are symptoms, change in disease status, and functional outcomes. This well-conducted RCT found that, although an increase in the hours of use per day was associated with a reduction in the time to healing, there was no difference in the rate of healing between treatment and placebo. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have had surgery of the appendicular skeleton who receive noninvasive electrical bone growth stimulation, the evidence includes 2 small RCTs. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Although the results of 1 trial suggest benefits to the bone stimulation in decreased time to union, clinical outcomes were not assessed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Implantable and Semi-Invasive Bone Growth Stimulation
For individuals who have fracture, pseudarthrosis, or who have had surgery of the appendicular skeleton who receive implantable and semi-invasive electrical bone growth stimulation, the evidence includes a small number of case series. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Policy

Coding Information

Click the links below for attachments, coding tables & instructions.
Attachment I- CPT® Coding Table
Attachment II- ICD-10-CM Coding Table

When a service may be considered medically necessary

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as treatment of fracture nonunions or congenital pseudoarthrosis in the appendicular skeleton (the appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities). The diagnosis of fracture nonunion must meet **ALL** of the following criteria:

- at least 3 months have passed since the date of fracture; **AND**
- serial radiographs have confirmed that no progressive signs of healing have occurred; **AND**
- the fracture gap is 1 cm or less; **AND**
- the patient can be adequately immobilized; **AND**

- the patient is of an age likely to comply with nonweight bearing for fractures of the pelvis and lower extremities.

When a service is considered investigational

Investigational applications of electrical bone growth stimulation include, but are not limited to, immediate postsurgical treatment after appendicular skeletal surgery, stress fractures, or for the treatment of fresh fractures, delayed union, arthrodesis, or failed arthrodesis.

Implantable and semi-invasive electrical bone growth stimulators are considered **investigational**.

Definitions:

Fresh Fracture
A fracture is most commonly defined as "fresh" for 7 days after the fracture occurs. Most fresh closed fractures heal without complications with the use of standard fracture care (ie, closed reduction and cast immobilization).

Delayed Union
Delayed union is defined as 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 site for no less than 3 months from the index injury or the most recent intervention. In contrast, nonunion serial radiographs (described next) show no evidence of healing. When lumped together, delayed union and nonunion are sometimes referred to as "un-united fractures."

Fractured Nonunion
No consensus on the definition of fracture nonunion currently exists. One proposed definition is failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months following the fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight bearing) (Bhandari et al, 2012).

The original U.S. Food and Drug Administration (FDA) labeling of fracture non-unions defined non-unions as fractures not showing progressive healing after at least 9 months from the original injury. The labeling states: "A nonunion is considered to be established when a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for minimum of 3 months." This timeframe is not based on physiologic principles but was included as part of the research design for FDA approval as a means of ensuring homogeneous populations of patients, many of whom were serving as their own controls. Others have contended that 9 months represents an arbitrary cutoff point that does not reflect the complicated variables present in fractures, (i.e., degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock). Some fractures may show no signs of healing, based on serial radiographs as early as 3 months, while a fracture nonunion may not be diagnosed in others until well after 9 months. The current policy of requiring a 3-month timeframe for lack of progression of healing is consistent with the definition of nonunion as described in

the clinical literature.

Reference Resources

1. BCBSA MPRM 7.01.07 - Electrical Stimulation of the Appendicular Skeleton. Last reviewed 05/2023. Accessed 7/2023.

Related Policies

Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer's benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member's contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non- compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required for services outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member's health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member's benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member's benefit.

Coverage varies according to the member's group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services Only (ASO) group, benefits may vary or not apply. To verify benefit information, please refer to the member's employer benefit plan documents or contact the customer service department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

Policy Implementation/Update Information

04/2017	Adopted BCBSA policy MPRM 7.01.07
10/2017	Updated description, updated regulatory status, updated references, added Related Policy section, added ICD-10 Q74.0 to the coding table. Policy Statement remains unchanged.
01/2019	Aligned with BCBSA MPRM 7.01.07 updated references, policy statements remain unchanged.
09/2021	Policy reviewed. Description/Summary updated. References simplified as policy references BCBSA MPRM 7.01.07. Policy statement unchanged.
08/2022	Policy reviewed; reference updated. Policy statement unchanged.
07/2023	Policy reviewed. Reference updated. No change in policy statement.

Eligible providers

Qualified healthcare professionals practicing within the scope of their license(s).

Approved by BCBSVT Medical Directors

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Senior Medical Director

Attachment I
CPT® Coding Table

Code Type	Number	Description	Policy Instructions
The following codes will be considered as medically necessary when applicable criteria have been met.			
CPT®	20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)	Prior Approval is required
HCPCS	E0747	Osteogenesis stimulator, electrical, noninvasive, other than spinal applications	Prior Approval is required
The following codes will be denied as Not Medically Necessary, Non-Covered, Contract Exclusions or Investigational			
CPT®	20975	Electrical stimulation to aid bone healing; invasive (operative)	Investigational
HCPCS	E0749	Osteogenesis stimulator, electrical, surgically implanted	Investigational

Attachment II
ICD- 10-CM Table

ICD-10 code	Description
The following codes are considered medically necessary when applicable criteria is met.	
Q74.0	Other congenital malformations of upper limb(s), including shoulder Girdle (includes congenital pseudoarthrosis of clavicle)
S32.2xxK-S32.9xxK	Fracture of coccyx
S42.00xK-S42.92xK	Fracture of shoulder and upper arm
S49.00xK-S49.199K	Other and unspecified injuries of shoulder and upper arm
S52.00xK-S52.92xN	Fracture of forearm

S59.00xK- S59.299K	Other and unspecified injuries of elbow and forearm
S62.00xK- S62.92xK-	Fracture at wrist and hand level
S72.00xK- S72.92xN	Fracture of femur
S79.00xK- S79.199K	Other and unspecified injuries of hip and thigh
S82.00xK- S82.92xN	Fracture of lower leg, including ankle
S89.00xK- S89.399K	Other and unspecified injuries of lower leg
S92.00xK- S92.919K	Fracture of foot and toe, except ankle
Fracture nonunion codes for the appendicular skeleton – 7th digit "K" is subsequent encounter for nonunion (in forearm, femur, lower leg & ankle fractures 7th digits "M" and "N" are also nonunion for certain types of open fractures – in fractures of the shoulder, humerus, wrist, hand, and foot with no mention of separation of open vs. closed non-unions).	