



An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 04/16/24
LAST REVIEW DATE: 04/16/24
CURRENT EFFECTIVE DATE: 04/16/24
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NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

ELECTRICAL BONE GROWTH STIMULATION OF THE APPENDICULAR SKELETON

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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ELECTRICAL BONE GROWTH STIMULATION OF THE APPENDICULAR SKELETON

Description:

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 pseudarthrosis, and arthrodesis.

Electrical and Electromagnetic Bone Growth Stimulators

Different applications of electrical and electromagnetic fields have been used to promote healing of delayed and nonunion fractures: invasive, noninvasive, and semi-invasive.

Invasive stimulation involves the surgical implantation of a cathode at the fracture site to produce direct current electrical stimulation. Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, while an electrode is implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for 6 to 9 months after implantation, and although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and worn for 24 hours a day until healing occurs or up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils placed over the skin and worn for 6 to 8 hours a day for 3 to 6 months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying magnetic field onto an additional static magnetic field. This device involves a 30-minute treatment per day for 9 months. Individual compliance may be an issue with externally worn devices.

In 1984, the noninvasive OrthoPak® Bone Growth Stimulator was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process for treatment of fracture nonunion. Pulsed electromagnetic field systems with the FDA premarket approval (all noninvasive devices) include Physio-Stim® first approved in 1986, and OrthoLogic® 1000, approved in 1997, both indicated for the treatment of established nonunion secondary to trauma, excluding vertebrae and all flat bones, in which the width of the nonunion defect is less than one-half the width of the bone to be treated; and the EBI Bone Healing System®, which was first approved in 1979 and indicated for nonunions, failed fusions, and congenital pseudarthrosis. No distinction was made between long and short bones. The FDA has approved labeling changes for electrical bone growth stimulators that remove any time frame for the diagnosis. As of September 2020, under consideration is the reclassification of noninvasive electrical bone growth stimulators from Class III to the lower-risk Class II category.

No semi-invasive electrical bone growth stimulator devices with the FDA approval or clearance were identified.



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Definitions:

Appendicular skeleton: The appendicular skeleton includes the bones of the shoulder girdle, upper extremities, pelvis, and lower extremities.

Delayed union: Delayed union is fracture healing that takes longer than normal.

Fracture nonunion: Fracture nonunion is the fracture did not heal.

Criteria:

- Noninvasive electrical bone growth stimulation is considered **medically necessary** with documentation of **ANY** of the following:
 1. Delayed union or fracture nonunions in the appendicular skeleton with documentation of **ALL** of the following:
 - At least 3 months have passed since the date of fracture
 - Serial radiographs have confirmed that no progressive signs of healing have occurred
 - Individual can be adequately immobilized
 - Individual is of an age likely to comply with nonweight bearing for fractures of the pelvis and lower extremities
 2. Congenital pseudarthrosis in the appendicular skeleton
- Other applications of electrical bone growth stimulation are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
 1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

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These applications include, *but are not limited to*:

- Fresh fracture
 - Stress fractures
 - Immediate postsurgical treatment after appendicular skeletal surgery
 - Arthrodesis
 - Failed arthrodesis
- Implantable and semi-invasive electrical bone growth stimulators are considered **experimental or investigational** when any **ONE** or more of the following criteria are met:
1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
 2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
 3. Insufficient evidence to support improvement of the net health outcome; or
 4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, or
 5. Insufficient evidence to support improvement outside the investigational setting

Resources:

Literature reviewed 04/16/24. We do not include marketing materials, poster boards and non-published literature in our review.

1. Adie S, Harris IA, Naylor JM, et al. Pulsed electromagnetic field stimulation for acute tibial shaft fractures: a multicenter, double-blind, randomized trial. *J Bone Joint Surg Am*. Sep 7 2011;93(17):1569-76. doi:10.2106/jbjs.J.00869
2. Ahl T, Andersson G, Herberts P, Kalén R. Electrical treatment of non-united fractures. *Acta Orthop Scand*. Dec 1984;55(6):585-8. doi:10.3109/17453678408992400
3. 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*. Aug 19 2016;6:31724. doi:10.1038/srep31724
4. Barker AT, Dixon RA, Sharrard WJ, Sutcliffe ML. Pulsed magnetic field therapy for tibial non-union. Interim results of a double-blind trial. *Lancet*. May 5 1984;1(8384):994-6. doi:10.1016/s0140-6736(84)92329-8
5. Beck BR, Matheson GO, Bergman G, et al. Do capacitively coupled electric fields accelerate tibial stress fracture healing? A randomized controlled trial. *Am J Sports Med*. Mar 2008;36(3):545-53. doi:10.1177/0363546507310076

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6. Bhandari M, Fong K, Sprague S, Williams D, Petrisor B. Variability in the definition and perceived causes of delayed unions and nonunions: a cross-sectional, multinational survey of orthopaedic surgeons. *J Bone Joint Surg Am.* Aug 1 2012;94(15):e1091-6. doi:10.2106/jbjs.K.01344
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9. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Osteogenic Stimulators (150.2). 2005. Accessed March 5, 2023. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=65>
10. Connolly JF. Selection, evaluation and indications for electrical stimulation of ununited fractures. *Clin Orthop Relat Res.* Nov-Dec 1981;(161):39-53.
11. Connolly JF. Electrical treatment of nonunions. Its use and abuse in 100 consecutive fractures. *Orthop Clin North Am.* Jan 1984;15(1):89-106.
12. de Haas WG, Beaupré A, Cameron H, English E. The Canadian experience with pulsed magnetic fields in the treatment of ununited tibial fractures. *Clin Orthop Relat Res.* Jul 1986;(208):55-8.
13. Dhawan SK, Conti SF, Towers J, Abidi NA, Vogt M. The effect of pulsed electromagnetic fields on hindfoot arthrodesis: a prospective study. *J Foot Ankle Surg.* Mar-Apr 2004;43(2):93-6. doi:10.1053/j.fas.2004.01.007
14. Faldini C, Cadossi M, Luciani D, Betti E, Chiarello E, Giannini S. Electromagnetic bone growth stimulation in patients with femoral neck fractures treated with screws: prospective randomized double-blind study. *Current Orthopaedic Practice.* 2010;21:282-287.
15. 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.* Apr 13 2011;(4):Cd008471. doi:10.1002/14651858.CD008471.pub2
16. Griffin XL, Warner F, Costa M. The role of electromagnetic stimulation in the management of established non-union of long bone fractures: what is the evidence? *Injury.* Apr 2008;39(4):419-29. doi:10.1016/j.injury.2007.12.014
17. Hannemann PF, Göttgens KW, van Wely BJ, et al. The clinical and radiological outcome of pulsed electromagnetic field treatment for acute scaphoid fractures: a randomised double-blind placebo-controlled multicentre trial. *J Bone Joint Surg Br.* Oct 2012;94(10):1403-8. doi:10.1302/0301-620x.94b10.28844

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25. Sharrard WJ, Sutcliffe ML, Robson MJ, Maceachern AG. The treatment of fibrous non-union of fractures by pulsing electromagnetic stimulation. *J Bone Joint Surg Br.* 1982;64(2):189-93. doi:10.1302/0301-620x.64b2.6978339
26. Shi HF, Xiong J, Chen YX, et al. Early application of pulsed electromagnetic field in the treatment of postoperative delayed union of long-bone fractures: a prospective randomized controlled study. *BMC Musculoskelet Disord.* Jan 19 2013;14:35. doi:10.1186/1471-2474-14-35
27. Simonis RB, Parnell EJ, Ray PS, Peacock JL. Electrical treatment of tibial non-union: a prospective, randomised, double-blind trial. *Injury.* May 2003;34(5):357-62. doi:10.1016/s0020-1383(02)00209-7
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Coding:

CPT: 20974, 20975
HCPCS: E0747, E0749

<u>History:</u>	<u>Date:</u>	<u>Activity:</u>
Medical Policy Panel	04/16/24	Approved guideline
Clinical Advisor (Dr. Brimacombe)	04/03/24	Development
Medical Director (Dr. Raja, Dr. Sutanto)	03/07/24	Development
Medical Director (Dr. Raja)	02/15/24	Development

Policy Revisions:



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Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nilinígíí Blue Cross Blue Shield of Arizona haada yit'éego bina'idíílkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yina'idíílkidgo beehaz'áanii hólg díí t'áa hazaadk'ehjí háká a'doowołgo bee haz'ą doo baqah ilinígóó. Ata' halne'ígíí kojí' bich'í' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:

إن كان لديك أو لدى شخص تساعد أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون أية تكلفة. للتحدث مع مترجم اتصل بـ 877-475-4799.



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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulongan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi: اگر شما، یا کسی که شما به او کمک میکنید، سوال در مورد Blue Cross Blue Shield of Arizona، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799 [تماس حاصل نمایید.]

Assyrian: Blue Cross Blue Shield of Arizona ... 877-475-4799

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคน หรือคนทอดกลางช่วยเหลื่อมคาถามเกยวกับ Blue Cross Blue Shield of Arizona คนสมทททจะไตรงความช่วยเหลอมและขอมลในภาษา ของคนใดโดยไมมคาไจจ่าย พดคยภมลาม โทร 877-475-4799