

Corporate Medical Policy

Ultrasound Accelerated Fracture Healing Device

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| File Name: | ultrasound_accelerated_fracture_healing_device |
| Origination: | 12/1994 |
| Last CAP Review: | 2/2012 |
| Next CAP Review: | 2/2013 |
| Last Review: | 2/2012 |

Description of Procedure or Service

Low-intensity pulsed ultrasound had been principally investigated as a technique to accelerate healing of fresh fractures, but more recently has been assessed as a treatment of fracture nonunions. Ultrasound can be delivered noninvasively with the use of a transducer applied to the skin surface overlying the fracture site. Ultrasound treatment can be self-administered with one daily 20-minute treatment, continuing until the fracture has healed. The mechanism of action at the cellular level is not precisely known, but is thought to be related to a mechanical effect on cell deformation or indirectly by an electrical effect caused by cell deformation. The ultimate effect on fracture healing may be mediated by enhanced vascularity at the fracture site or enhanced chondrocyte maturation.

The Sonic Accelerated Fracture Healing System, SAFHS ® (also referred to as Exogen 2000®) was initially cleared for marketing by the U.S. Food and Drug Administration (FDA) in October 1994 as a treatment of fresh, closed, posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade 1 open tibial diaphysis fractures in skeletally mature individuals when these fractures are orthopedically managed by closed reduction and cast immobilization. In February 2000, the labeled indication was expanded to include the treatment of established nonunions, excluding skull and vertebra. According to the FDA labeling, a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

Please note related policy titled, "Electrical Bone Growth Stimulation."

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Ultrasound Accelerated Fracture Healing Device when it is determined to be medically necessary because the medical criteria and guidelines shown below are met.

Benefits Application

Please refer to certificate for availability of benefit. See Professional Services, Outpatient Services, Durable Medical Equipment (DME). This policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

DME Supplier must meet eligibility and/or credentialing requirements as defined by the Plan in order to be eligible for reimbursement.

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The individual certificate should be reviewed to verify eligibility requirements and any prior approval or preauthorization necessary for the rental/purchase of equipment.

When Ultrasound Accelerated Fracture Healing Device is covered

Low-intensity ultrasound treatment may be considered medically necessary when used as an adjunct to conventional management (including, but not limited to, closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals.

Low-intensity ultrasound treatment may be considered medically necessary as a treatment of fracture non-unions of bones excluding the skull and vertebrae.

Low-intensity ultrasound treatment may be considered medically necessary as a treatment of delayed union of bones, excluding the skull and vertebrae.

When Ultrasound Accelerated Fracture Healing Device is not covered

Other applications of low intensity ultrasound treatment are investigational, including but not limited to, congenital pseudoarthroses, open fractures, or stress fractures.

This device may not be used concurrently with other noninvasive devices.

Policy Guidelines

The most appropriate candidates for ultrasound treatment of fresh fractures are those at high risk for delayed fracture healing, delayed union, or nonunion. These risk factors may include both locations of fractures and patient comorbidities and include the following:

Patient comorbidities:

- Diabetes
- Steroid therapy
- Osteoporosis
- History of alcoholism
- History of smoking

Fracture locations:

- Jones fracture
- Fracture of navicular bone in the wrist (also called the scaphoid)
- Fracture of metatarsal
- Fractures associated with extensive soft tissue or vascular damage

Fresh Fractures:

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, i.e., 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.

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Nonunions:

The FDA labeling simply suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without giving any guidance regarding the time frame of observation. However, it is suggested that a reasonable time period for lack of visible signs of healing is 3 months. The following patient selection criteria are suggested, consistent with those proposed for electrical stimulation as a treatment of nonunions:

- At least 3 months have passed since the date of the fracture, AND
- Serial radiographs have confirmed that no progressive signs of healing have occurred, AND
- The fracture gap is 1cm or less, AND
- The patient can be adequately immobilized and is of an age when he/she is likely to comply with non-weight bearing.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: E0760, 20979

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Consultant Review, 11/94

TEC Evaluation, 9/95

Independent Review, Vice-President Medical Affairs, 9/98

Specialty Matched Consultant Advisory Panel - 11/1999

Medical Policy Advisory Group - 12/2/1999

BCBSA Medical Policy Reference Manual, 8/18/00, 1.01.05

HCFA Website accessed on 10/3/2000, www.hcfa.gov/quality, Ultrasound Stimulation for Nonunion Fracture Healing document dated 8/30/2000

Medical Policy Advisory Group - 10/2000

BCBSA Medical Policy Reference Manual, 12/15/00; 1.01.05

Busse, J.W., Bhandari, M., Kulkarni, A. V., and Tunks, E. The effect of low-intensity pulsed ultrasound therapy on time to fracture healing: a meta-analysis. *CMAJ* 2002 Feb. 19; 166(4):437-41. *ECRI*: May, 13, 2002.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 2/25/04

Specialty Matched Consultant Advisory Panel - 7/2004

Agency for Healthcare Research and Quality (AHRQ) Technology Assessment Program (September 2005). The Role of Bone Growth Stimulating Devices and Orthobiologics in Healing Nonunion Fractures. Retrieved April 28, 2006 from <http://www.cms.hhs.gov/coverage/download/id.30M.pdf>

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BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 6/27/05

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 2/14/08

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 9/10/09

For Policy Renamed: Ultrasound Accelerated Fracture Healing Device:

Washington State Health Care Authority Health Technology Assessment. Bone Growth Stimulators. July 2009. Retrieved on June 3, 2010 from http://www.hta.hca.wa.gov/documents/bgs_final_report_073109_updated.pdf

Specialty Matched Consultant Advisory Panel review 7/2010

National Institute for Health and Clinical Excellence (NICE). Low-intensity pulsed ultrasound to promote fracture healing. Interventional procedure guidance 374. December 2010. Retrieved on February 1, 2011 from <http://www.nice.org.uk/nicemedia/live/12408/52076/52076.pdf>

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 1/13/11

Specialty Matched Consultant Advisory Panel review 2/2011

Schofer MD, Block JE, Aigner J et al. Improved healing response in delayed unions of the tibia with low-intensity pulsed ultrasound: results of a randomized sham-controlled trial. *BMC Musculoskelet Disord* 2010; 11:229.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 9/1/11

Specialty Matched Consultant Advisory Panel review 2/2012

Policy Implementation/Update Information

For policy named: Sonic Accelerated Fracture Healing System (SAFHS):

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| 9/95 | Revised: Eligible for coverage for fresh, closed, or Grade I open tibial diaphysis fractures or fresh, closed posteriorly displaced distal radius (Colles') fractures in skeletally mature individuals. |
| 10/96 | Reaffirmed. |
| 5/99 | Reformatted, "Description of Procedure or Service" changed, Medical Term Definitions added. |
| 12/99 | Reviewed by Specialty Matched Consultant Advisory Panel and Medical Policy Advisory Group. Recommended removing procedure from covered services. Medicare has withdrawn approval of the procedure, because it has not proven to be effective. Policy changed to not covered due to not medically necessary. |
| 2/00 | 20979 added to coding section. |
| 9/00 | System coding changes. |
| 10/00 | Revised. Policy changed from investigational to eligible for coverage for specific criteria. |
| 10/00 | Medical Policy Advisory Group - Approved. |
| 1/01 | Revised. Under Policy Guidelines section, bullet number 4, changed the term, "mobilized" to "immobilized". |
| 9/02 | Revised section under when it is covered. Removed the statement, "when used as an adjunct to conventional management (e.g., closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals." The statement now includes specific bone types. Additional criteria added for non-unions. Also revised to include specific |

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- criteria for review to include high risk patients for delayed fracture healing or non-union. Policy Guidelines section removed. These guidelines are included in the "when it is covered" section of the policy.
- 8/12/04 Specialty Matched Consultant Advisory Panel review 07/15/2004 with no changes to policy criteria. Benefit Applications and Billing/Coding sections updated for consistent policy language. References added.
- 7/07/2005 Requirement for documented failure of at least one open surgical intervention for the treatment of the fracture removed from coverage criteria section.
- 12/01/05 Revised section When SAFHS is covered. Removed statement regarding treatment of "posteriorly displaced distal radius (Colles') fractures and fresh, closed, or grade 1 open tibial diaphysis fractures." Added additional indications to statement regarding patients at high risk for delayed fracture healing. Added "open fractures" to section When SAFHS is not covered. Added key words.
- 8/21/06 References updated. Specialty Matched Consultant Advisory Panel review 7/24/06. No changes to policy criteria. (adn)
- 8/25/08 When Covered section reformatted to numbered list. Item 1 revised to read: when used as an adjunct to conventional management (including, but not limited to, closed reduction and cast immobilization) for the treatment of fresh (less than a month old), closed fractures in skeletally mature individuals. The following sentence in Item 3 revised to read: Also at high risk are those with Jones fracture (base of 5th metatarsal), fracture of navicular (scaphoid) bone in the wrist... References updated. Specialty Matched Consultant Advisory Panel review 7/17/08. No change to policy statement. (adn)

For Policy Renamed: Ultrasound Accelerated Fracture Healing Device:

- 2/2/10 Policy name changed from Sonic Accelerated Fracture Healing System (SAFHS) to Ultrasound Accelerated Fracture Healing Device. Description section extensively revised. When Covered section revised to read: Low-intensity ultrasound treatment may be considered medically necessary when used as an adjunct to conventional management (i.e., closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals and as a treatment of fracture nonunions of bones, excluding the skull and vertebra. When Not Covered section revised to read: "Other applications of low-intensity ultrasound treatment are investigational, including but not limited to treatment of delayed unions (defined as a decelerating healing process as determined by serial x-rays), congenital pseudoarthrosis, open fractures, or **stress fractures**. This device may not be used concurrently with other noninvasive devices." Information that was previously in the When Covered section was moved to the Policy Guidelines section. Notification given 2/2/10 for effective date of 5/11/10. (adn)
- 8/17/10 Specialty Matched Consultant Advisory Panel review 7/2010. Medical Policy number removed. References updated. (mco)
- 3/15/11 Specialty Matched Consultant Advisory Panel review 2/2011. Revised Policy Statement from "BCBSNC will provide coverage for Sonic Accelerated Fracture Healing system when it is determined to be medically necessary because the medical criteria and guidelines shown below are met." to "BCBSNC will provide coverage for Ultrasound Accelerated Fracture Healing Device when it is determined to be medically necessary because the medical criteria and guidelines shown below are met." References updated. (mco)
- 11/8/11 Policy Statement updated. New statement in section "When Covered" states: "Low-intensity ultrasound treatment may be considered medically necessary as a treatment of delayed union of bones, (defined as a decelerating healing process as determined by serial x-rays), excluding the skull and vertebra." Revised statement in section "When not Covered" to state: "Other applications of low intensity ultrasound treatment are investigational, including but not limited to , congenital pseudoarthroses, open fractures, or stress fractures." Removed

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“delayed unions of bones” from the “When not Covered” section. Policy Guidelines updated to include information regarding delayed unions. References updated. Reviewed by Medical Director 10/2011. (mco)

3/20/12 Removed “less than one month old” from “When not Covered” section. Statement now revised as follows: “Low-intensity ultrasound treatment may be considered medically necessary when used as an adjunct to conventional management (including, but not limited to, closed reduction and cast immobilization) for the treatment of fresh, closed fractures in skeletally mature individuals.” Removed definition of delayed union “(defined as a decelerating healing process as determined by serial x-rays)” from “When Covered” section. Revised “Policy Guidelines.” Specialty Matched Consultant Advisory Panel review 2/2012. Medical Director review 2/2012. (mco)

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.