Corporate Medical Policy

Ultrasound Accelerated Fracture Healing Device

File Name: ultrasound_accelerated_fracture_healing_device
Origination: 12/1994
Last Review: 2/2024

Description of Procedure or Service

Low-intensity pulsed ultrasound has been investigated as a technique to accelerate healing of fresh fractures, delayed unions, nonunions, stress fractures, osteotomy sites, and distraction osteogenesis. Ultrasound is delivered noninvasively with the use of a transducer applied to the skin surface overlying the fracture site.

The majority of bone fractures heal spontaneously over the course of several months following standard fracture care. However, approximately 5%-10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services. Ultrasound may accelerate healing of fractures by stimulating new bone growth, and therefore, has been proposed as a treatment for fractures with delayed healing or at high risk for non-healing.

The current policy does not limit the use of the device to specific fracture sites. Depending on their function, bones are composed of a varying combination of cortical and trabecular bone. However, at the cellular level, the type of bone cannot be distinguished histologically. The inclusion of all bones regardless of the anatomic site is based on this histologic similarity of all bones; it is not anticipated that the efficacy of ultrasound-accelerated healing would vary according to the anatomic site and function of the bone.

The definition of a fracture nonunion has remained controversial. For electrical bone growth stimulators (see policy titled, “Electrical Bone Growth Stimulation”), The original U.S. Food and Drug Administration (FDA) labeling of fracture nonunions defined them 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 time frame 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 (ie, degree of soft tissue damage, alignment of the bone fragments, vascularity, 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 9months. According to the FDA labeling for a low-intensity pulsed ultrasound device, “a nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.”

Delayed union is generally considered a failure to heal between 3 and 9 months after fracture, after which the fracture site would be considered to be a nonunion. Delayed union may also be defined as a decelerating bone healing process, as identified in serial radiographs. (In contrast, nonunion serial radiographs show no evidence of healing.) Together, delayed union and nonunion are sometimes referred to as "ununited fractures." To determine the status of fracture healing, it is important to include both radiographic and clinical criteria. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

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 micromotion/deformation, causing an increase in stimulation of transmembrane cell adhesion molecules and upregulation of cyclooxygenase-2.

The Sonic Accelerated Fracture Healing System, SAFHS ® (also referred to as Exogen 2000® and since 2006, Exogen 4000+; Bioventus) 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. The AccelStim™ Bone Growth Stimulator (Orthofix US) was FDA approved in 2022 for accelerating time to healed fracture for fresh, closed, posteriorly displaced distal radius fractures and fresh, closed, or Grade I open tibial diaphysis fractures and for established non-unions in skeletally mature adults.

Related Policies:
Electrical Bone Growth Stimulation
Bone Morphogenetic Protein

******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.

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 pulsed ultrasound 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 pulsed ultrasound may be considered medically necessary as a treatment of fracture non-unions of bones, including nonunion of previously surgically treated fractures, and excluding the skull and vertebrae.

Low-intensity pulsed ultrasound may be considered medically necessary as a treatment of delayed union of bones, including delayed union of previously surgically treated fractures, and excluding the skull and vertebrae.

When Ultrasound Accelerated Fracture Healing Device is not covered

Other applications of low intensity pulsed ultrasound are investigational, including but not limited to, treatment of congenital pseudoarthroses, open fractures, fresh surgically-treated closed fractures, arthrodesis, failed arthrodesis, 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 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 for no less than 3 months from the index injury or the most recent intervention.

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.

For individuals who have fresh closed fractures who receive low intensity pulsed ultrasound, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant

outcomes are symptoms, morbid events, functional outcomes, and quality of life. This evidence indicates that low intensity pulsed ultrasound improves clinical and radiographic healing for fresh closed fractures, although the magnitude of benefit may differ depending on the location of the bone and risk factors for healing. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have open fractures or surgically treated closed fractures who receive low intensity pulsed ultrasound, the evidence includes RCTs. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Results from RCTs of low intensity pulsed ultrasound for this patient population are mixed, and do not consistently demonstrate improved outcomes. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fracture nonunion who receive low intensity pulsed ultrasound, the evidence includes prospective case series. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The case series are considered adequate evidence for nonunions, due to the negligible chance of healing without intervention and the lack of other noninvasive alternatives. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have delayed fracture union who receive low intensity pulsed ultrasound, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Evidence for US treatment for delayed fracture union (a moderately sized double-blinded sham-controlled trial) showed a moderate effect size for increased bone mineral density and a trend toward increased rate of clinical healing with US treatment. In addition, improvements in intermediate outcomes (eg, radiographic appearance), combined with the efficacy of US for fresh closed fractures and fracture nonunion, make it very likely that this treatment is also efficacious for delayed union. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

For individuals who have tibial stress fractures, osteotomy sites, or distraction osteogenesis who receive low intensity pulsed ultrasound, the evidence includes small RCTs and nonrandomized comparative trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. One small RCT was identified on US for the treatment of tibial stress fractures. Low intensity pulsed ultrasound did not significantly reduce healing time for these fractures in this double-blind study. One small quasi-randomized study was identified on use of US for osteotomy sites. Clinical outcomes appear to have been assessed only at the time of radiographic healing and did not show any differences between groups at that time point. The literature on pulsed US for distraction osteogenesis (small trials) has shown inconsistent results. The evidence is insufficient to determine the effects of the technology on health outcomes.

Most fresh closed fractures heal without complications using standard fracture care (ie, closed reduction and cast immobilization). Therefore, US treatment will improve outcomes most in those with closed fractures at high risk for delayed fracture healing or nonunion. Risk factors for reduced healing, determined in part through clinical input, include diabetes, steroid therapy, osteoporosis, alcoholism, and smoking, along with some fracture locations. Factors found to reduce healing rate in a postmarketing registry included open fracture, current smoking, diabetes, vascular insufficiency, osteoporosis, cancer, rheumatoid arthritis, and prescription nonsteroidal anti-inflammatory drugs.

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

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

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 9/10/12

Specialty Matched Consultant Advisory Panel review 2/2013

Dijkman BG, Busse JW, Walter SD et al. The impact of clinical data on the evaluation of tibial fracture healing. Trials 2011; 12:237. http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3254075/

National Institute for Health and Care Excellence. NICE medical technology guidance 12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing. 2013. http://www.nice.org.uk/nicemedia/live/14018/62289/62289.pdf.

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 12/12/13

Specialty Matched Consultant Advisory Panel review 2/2014

Medical Director review 2/2014

Specialty Matched Consultant Advisory Panel review 2/2015

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 2/12/15

Specialty Matched Consultant Advisory Panel review 2/2015

Specialty Matched Consultant Advisory Panel review 2/2016

BCBSA Medical Policy Reference Manual [Electronic Version]. 1.01.05, 8/11/16

Specialty Matched Consultant Advisory Panel review 2/2017

Specialty Matched Consultant Advisory Panel review 2/2018

Specialty Matched Consultant Advisory Panel review 2/2019

Specialty Matched Consultant Advisory Panel review 2/2020

Specialty Matched Consultant Advisory Panel review 2/2021

Specialty Matched Consultant Advisory Panel review 2/2022

Specialty Matched Consultant Advisory Panel review 2/2023

National Institute for Health and Care Excellence. NICE medical technology guidance 12: EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing 2019 https://www.nice.org.uk/guidance/mtg12/resources/exogen-ultrasound-bone-healing-system-for-long-bone-fractures-with-nonunion-or-delayed-healing-pdf-64371871020229

Specialty Matched Consultant Advisory Panel review 2/2024

Medical Director review 2/2024

Policy Implementation/Update Information

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

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 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 pseudarthrosis, 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 "delayed unions of bones" from the "When not Covered" section. Policy Guidelines updatedto 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)

11/27/12 Revised following statement in the "When not Covered" section: "Other applications of low intensity ultrasound treatment are investigational, including but not limited to, congenital pseudoarthroses, open fractures, **arthrodeses**, or stress fractures." Policy Guidelines updated. Medical Director review 11/2012. Policy noticed 11/27/12 for effective date 2/26/2013. (mco)

3/12/13 Specialty Matched Consultant Advisory Panel review 2/2013. References updated. No changes to Policy Statements. (mco)

3/11/14 Description section revised. "When not Covered" statement revised to include "failed arthrodesis" and "fresh surgically-treated closed fractures" as non-covered indications. References updated. Specialty Matched Consultant Advisory Panel review 2/2014. Medical Director review 2/2014. (mco)

4/28/15	Reference added. Specialty Matched Consultant Advisory Panel review 2/2015. No change to Policy statements. (sk)
4/1/16	Specialty Matched Consultant Advisory Panel review 2/24/2016. (sk)
12/30/16	Reference added. Policy Guidelines updated. (sk)
3/31/17	Specialty Matched Consultant Advisory Panel review 2/22/2017. Policy Guidelines updated. (sk)
4/27/18	Specialty Matched Consultant Advisory Panel review 2/28/2018. (sk)
3/12/19	Specialty Matched Consultant Advisory Panel review 2/20/2019. (sk)
3/10/20	Specialty Matched Consultant Advisory Panel review 2/19/2020. (sk)
3/9/21	Specialty Matched Consultant Advisory Panel review 2/17/2021. (sk)
3/8/22	Specialty Matched Consultant Advisory Panel review 2/16/2022. (sk)
3/7/23	Specialty Matched Consultant Advisory Panel review 2/15/2023. (sk)
4/1/24	Description Section updated with new FDA definition of Non-union. Added Information regarding The AccelStim™ Bone Growth Stimulator. Updated references. Specialty Matched Consultant Advisory Panel review 2/2024. Medical Director review 2/2024. (rp)