BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 1.01.05 Low Intensity Pulsed Ultrasound Fracture Healing Device

Effective Policy Date: July 1, 2023

Original Policy Date: March 2012

Related Policies:

7.01.07 - Electrical Bone Growth Stimulation of the Appendicular Skeleton
7.01.85 - Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

Low Intensity Pulsed Ultrasound Fracture Healing Device

Description

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Low-intensity pulsed ultrasound has been investigated as a technique to accelerate healing of fresh fractures, surgically treated closed fractures, delayed unions, nonunions, stress fractures, osteotomy sites, and distraction osteogenesis. Low-intensity pulsed ultrasound is administered using a transducer applied to the skin surface overlying the fracture site.

OBJECTIVE

The objective of this evidence review is to evaluate whether, compared with routine care without low-intensity pulsed ultrasound, low-intensity pulsed ultrasound improves the net health outcome when used as an adjunct to routine care to treat fractures (including fresh fractures, surgically treated closed fractures, delayed unions, nonunions, stress fractures, osteotomy sites, and distraction osteogenesis).

POLICY STATEMENT

Low-intensity pulsed ultrasound is considered **not medically necessary** as a treatment of fresh fractures (surgically managed or nonsurgically managed).

Low-intensity pulsed ultrasound is considered **not medically necessary** as a treatment of fracture nonunion and delayed union fractures.

Low-intensity pulsed ultrasound is considered **not medically necessary** as a treatment of stress fractures, osteotomy, and distraction osteogenesis.

POLICY GUIDELINES

Fresh (Acute) Fracture

There is no standard definition for a "fresh" fracture. A fracture is most commonly defined as fresh for 7 days after the fracture occurs, but there is definitional variability. For example, one study defined fresh as less than 5 days after fracture, while another defined fresh as up to 10 days post-fracture. Most fresh closed fractures heal without complications using standard fracture care (ie, closed reduction and cast immobilization).

Nonunion

There is no consensus on the definition of nonunion. One definition is a failure of progression of fracture healing for at least 3 consecutive months (and at least 6 months post-fracture) accompanied by clinical symptoms of delayed/nonunion (pain, difficulty weight-bearing).

The definition of nonunion used in U.S. Food and Drug Administration (FDA) labeling suggests that nonunion is considered established when the fracture site shows no visibly progressive signs of healing, without providing guidance on the timeframe of observation. The following selection criteria are consistent with those proposed for electrical stimulation as a treatment of nonunions (see evidence review 7.01.07):

- 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 1 cm or less, and
- the individual can be adequately immobilized and, based on age, is likely to comply with non-weight bearing.

Delayed Union

Delayed union is defined as a decelerating healing process as determined by serial radiographs, 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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

The transducer used for ultrasound treatment is categorized as durable medical equipment.

FDA REGULATORY STATUS

In 1994, the Sonic Accelerated Fracture Healing System (SAFHS; renamed Exogen 2000 and Exogen 4000+, now Exogen Ultrasound Bone Healing System; Bioventus) was approved by the FDA through the premarket approval process for 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. FDA product code: LOF.

RATIONALE

Summary of Evidence

For individuals who have fresh fractures (surgically or nonsurgically managed) who receive low-intensity pulsed ultrasound as an adjunct to routine care, the evidence includes randomized controlled trials (RCTs) and several meta-analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The evidence base has evolved with the publication of a large RCT and meta-analysis significantly shifting the weight of the evidence. Conclusions based on several earlier and small RCTs, rated at high-risk of bias, showed a potential benefit; however, the large RCT published in 2016, rated at low-risk of bias, showed no benefit. A 2017 meta-analysis including only trials with low-risk of bias found no difference in days to full weight-bearing, pain reduction, or days to radiographic healing. Similarly, the overall results of the meta-analysis found no significant difference in return to work, subsequent operations, or adverse events. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have fracture nonunion or delayed union fracture who receive low-intensity pulsed ultrasound as an adjunct to routine care including surgery, if appropriate, the evidence includes only lower quality studies consisting of a small systematic review in scaphoid nonunions, a meta-analysis of nonunion in various locations, a meta-analysis in individuals with specific risk factors, 2 low-quality RCTs, and 1 observational comparative study. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Of the 2 RCTs, one did not include functional outcomes. The second RCT had a small sample size and did not describe the randomization procedure. The observational study reported similar healing rates with low-intensity pulsed ultrasound and surgery, although the retrospective nature of the study, limits meaningful interpretation of these results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have stress fractures, osteotomy sites, or distraction osteogenesis who receive low-intensity pulsed ultrasound as an adjunct to routine care, the evidence includes only lower quality studies consisting of small RCTs, retrospective comparative observational studies , and one meta-analysis for distraction osteogenesis. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Results do not generally include functional outcomes and results across various outcomes, primarily time to radiographic healing, are inconsistent. The meta-analysis of 3 trials using low-intensity pulsed ultrasound for distraction osteogenesis reported no statistically significant differences in physiological or functional outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

National Institute for Health and Care Excellence

In 2013, NICE published guidance on Exogen for the treatment of long-bone fractures with nonunion and delayed fracture healing.[31,] The NICE concluded that use of the Exogen bone healing system to treat long-bone fractures with nonunion is supported by "clinical evidence" and "cost savings ... through avoiding surgery." For long-bone fractures with delayed healing, defined as no radiologic evidence of healing after 3 months, there was "some radiologic evidence of improved healing." However, due to "substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture" and need for surgery, "cost consequences" were uncertain. In 2019, the Exogen guidance was updated with a review of studies published after June 2012.[31,] The review decision stated, "Overall the additional clinical evidence identified since the guidance was published in 2013 supports the current recommendations." The reviewers did not consider the Schandelmaier et al (2017) systematic review because it pooled fresh fractures and distraction osteogenesis alongside non-unions.

In 2018, NICE published guidance on the use of low-intensity pulsed ultrasound in 3 clinical circumstances, The guidance made the following conclusions:

- To promote healing of fresh fractures at low-risk of non-healing: "Current evidence does not show efficacy. Therefore, this procedure should not be used for this indication."[32,]
- To promote healing of fresh fractures at high-risk of non-healing: "Current evidence on efficacy is very limited in quantity and quality. Therefore, this procedure should only be used in the context of research."[33,]
- To promote healing of delayed and nonunion fractures: "Current evidence on efficacy is inadequate in quality. Therefore, this procedure should only be used with special arrangements for clinical governances, consent and audit or research."[34,]

American Academy of Orthopaedic Surgeons

In 2020, the American Academy of Orthopaedic Surgeons published updated guidelines on the treatment of distal radius fractures.[35,] Although the Academy issued a limited recommendation for the use of low-intensity pulsed ultrasound for adjuvant treatment of distal radius fractures in its prior 2009 guidelines, low-intensity pulsed ultrasound was not mentioned in the updated guidelines.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Effective 2001, ultrasonic osteogenic stimulators were covered as medically reasonable and necessary for the treatment of nonunion fractures.[36,] Nonunion fractures of the skull, vertebrae, and those that are tumor-related are excluded from coverage. Ultrasonic osteogenic stimulators may not be used concurrently with other noninvasive osteogenic devices. Ultrasonic osteogenic stimulators for fresh fractures and delayed unions are not covered.

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2012	New policy	
December 2012	Replace policy	Policy rationale and references updated; arthrodesis added to investigational statement; definition of delayed unions revised to 3 months for consistency with definition of nonunion.
March 2014	Replace policy	Policy updated with literature review. References 12, 16, and 18 added; clarification of non-union of previously surgically-treated fractures; fresh surgically-treated closed fractures added to Investigational statement.
March 2015	Replace policy	Policy updated with literature review; references 11 and 20 added. Information added to Policy Guidelines to clarify definition of "fresh fracture,. Policy statements unchanged.
December 2016	Replace policy	Policy updated with literature review through July 1, 2016; references 14 and 16 added. Policy statements unchanged.
September 2017	Replace policy	Policy updated with literature review through January 25, 2017;references 3-4, 7, 17, and 25-26 were added. The following indications were changed from medically necessary to not medically necessary: fresh fractures (surgically and nonsurgically managed) and nonunion/delayed union fractures.
June 2018	Replace policy	Policy updated with literature review through January 8, 2018; references 5-6 and 16-17 added. Policy statements are unchanged.
June 2019	Replace policy	Policy updated with literature review through February 27, 2019; references added. Policy statements unchanged.
June 2020	Replace policy	Policy updated with literature review through January 30, 2020; references updated. Policy statements unchanged. Title changed to "Low Intensity Pulsed Ultrasound Fracture Healing Device" to more accurately reflect the expanded labeled indications as per the Regulatory Status section.
June 2021	Replace policy	Policy updated with literature review through February 18, 2021; references added. Slightly revised practice guidelines section for clarity. Policy statements unchanged.
June 2022	Replace policy	Policy updated with literature review through February 3, 2022; no references added. Not medically necessary policy statements updated to investigational for policy standardization purposes; intent unchanged. Policy statements unchanged.
June 2023	Replace policy	Policy updated with literature review through January 17, 2023; references added. Minor editorial refinements to policy guidelines; intent unchanged.