MEDICAL POLICY

POLICY TITLE	LOW INTENSITY PULSED ULTRASOUND FRACTURE HEALING DEVICE
POLICY NUMBER	MP 6.021

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☒ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☐ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**2/1/2024**

I. POLICY

Low-intensity pulsed ultrasound are considered **not medically necessary** for treatment of the following**:**

- Fresh fractures (surgically managed or nonsurgically managed).
- Fracture nonunion and delayed union fractures.
- Stress fractures, osteotomy, and distraction osteogenesis.

There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

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 definition variability. For example, 1 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 (i.e., closed reduction and cast immobilization).

Nonunion

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

The definition of nonunion used in U.S. Food and Drug Administration 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 nonweight 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.

Cross-reference:

MP 1.024 Electrical Bone Growth Stimulation of the Appendicular Skeleton
MP 1.150 Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at: https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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Low-intensity pulsed ultrasound (LIPUS) 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. LIPUS is administered using a transducer applied to the skin surface overlying the fracture site.

Bone Fractures

An estimated 178 million new fractures were reported worldwide in 2019 . Most bone fractures heal spontaneously over the course of several months following standard fracture care (closed reduction if necessary, followed by immobilization with casting or splinting). However, approximately 5% to 10% of all fractures have delayed healing, resulting in continued morbidity and increased utilization of health care services. Factors contributing to a nonunion include

which bone is fractured, fracture site, degree of bone loss, time since injury, extent of soft tissue injury, and patient factors (e.g., smoking, diabetes, systemic disease).

Fracture Nonunion

There is no standard definition of a fracture nonunion. The Food and Drug Administration has defined nonunion as when “a minimum of 9 months has elapsed since injury and the fracture site shows no visibly progressive signs of healing for a minimum of 3 months." Other definitions cite 3 to 6 months of time from the original injury, or simply when serial radiographs fail to show any further healing. These definitions do not reflect the underlying conditions in fractures that affect healing, such as the degree of soft tissue damage, alignment of the bone fragments, vascularity, and quality of the underlying bone stock.

Delayed Union

Delayed union is generally considered a failure to heal between 3 and 9 months post fracture, after which the fracture site would be considered 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.) It is important to include both radiographic and clinical criteria to determine fracture healing status. Clinical criteria include the lack of ability to bear weight, fracture pain, and tenderness on palpation.

Treatment

Low-intensity pulsed ultrasound (LIPUS) has been proposed to accelerate healing of fractures. LIPUS is believed to alter the molecular and cellular mechanisms involved in each stage of the healing process (inflammation, soft callus formation, hard callus formation, and bone remodeling). The mechanism of action at the cellular level is not precisely known, but it is theorized that LIPUS may stimulate the production or the activities of the following compounds that contribute to the bone healing process: cyclooxygenase-2, collagenase, integrin proteins, calcium, chondroblasts, mesenchymal cells, fibroblasts, and osteoblasts.

LIPUS treatment is self-administered, once daily for 20 minutes, until the fracture has healed, usually for 5 months.

REGULATORY STATUS

In 1994, the Sonic Accelerated Fracture Healing System (SAFHS®; renamed Exogen 2000® and since 2006, Exogen 4000+; Bioventus) was approved by the U.S. Food and Drug Administration through the premarket approval process for treatment of fresh, closed, posteriorly displaced distal radius (Colles) fractures, and fresh, closed, or grade I 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. Food and Drug Administration product code: LPQ.

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IV. RATIONALE

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Summary of Evidence

For individuals who have fresh fractures (surgically or nonsurgically managed) who receive low-intensity pulsed ultrasound (LIPUS), the evidence includes randomized controlled trials (RCTs) and several meta-analysis. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. The evidence base has recently evolved with the publication of a large RCT and meta-analysis significantly shifting the weight of the evidence. Conclusions based on several earlier small RCTs, rated at high risk of bias, showed a potential benefit of LIPUS; 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 effect. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have fracture nonunion or delayed union fracture who receive LIPUS, the evidence includes only lower quality studies including 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 (LIPUS) as an adjunct to routine care, the evidence includes only lower quality studies including small RCTs. 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.

V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the

applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice, and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Low-intensity pulsed ultrasound is considered Not Medically Necessary: therefore, not covered:

Procedure Codes								
20979	E0760							

IX. REFERENCES

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X. POLICY HISTORY

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	CAC 05/27/2003

POLICY TITLE	LOW INTENSITY PULSED ULTRASOUND FRACTURE HEALING DEVICE
POLICY NUMBER	MP 6.021

MP 6.021	**CAC 07/29/2003**
	CAC 11/30/2004
	CAC 11/29/2005
	CAC 01/31/2006
	CAC 01/30/2007
	Policy approved for retirement effective 09/08/2008. See combined policy 1.024 Osteogenic Stimulators.
	CAC 07/26/2016 Policy **reinstated** to address Ultrasound Accelerated Fracture Healing Device as a stand-alone policy. This topic was previously addressed within MP-1.024. Policy statements unchanged. Background/Description, Policy Guidelines, Rationale, and Reference sections updated. Coding added. New diagnosis codes added effective 10/1/16
	10/01/2017 Administrative update. Revised ICD-10 code description effective from 10/1/17.
	01/01/2018 Administrative update. Medicare variations removed from Commercial Policies
	CAC 11/28/2017 Minor review. The following indications were changed from medically necessary to not medically necessary: fresh fractures (surgically and nonsurgically managed) and nonunion/delayed union fractures. Rationale and references updated. Coding reviewed.
	10/16/2018 Consensus. No change to policy statements. References updated. Rationale condensed.
	07/17/2019 Consensus review. No change to policy statements, references updated.
	06/26/2020 Consensus review. No change to policy statements, references updated.
	03/11/2021 Consensus review. No change to policy statement. References updated.
	04/20/2022 Consensus review. No change to policy statement. Coding table format updated. References reviewed and updated.
	3/29/2023 Consensus review. No change to policy statements. Background and rationale updated. References reviewed and updated. Coding reviewed.

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