Medical Policy

Ultrasound Accelerated Fracture Healing Device

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Policy Number: 497
BCBSA Reference Number: 1.01.05
NCD/LCD: Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

Related Policies
- Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures, #498
- Electrical Bone Growth Stimulation of the Appendicular Skeleton, #499
- Bone Morphogenetic Protein, #097

Policy

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

Low-intensity pulsed ultrasound may be considered NOT MEDICALLY NECESSARY as a treatment of fresh fractures (surgically managed or nonsurgically managed).

Low-intensity pulsed ultrasound may be considered NOT MEDICALLY NECESSARY as a treatment of fracture nonunion and delayed union fractures.

Low-intensity pulsed ultrasound may be considered NOT MEDICALLY NECESSARY as a treatment of stress fractures, osteotomy, and distraction osteogenesis.

Medicare HMO BlueSM and Medicare PPO BlueSM Members

Medical necessity criteria and coding guidance for Medicare Advantage members living in Massachusetts can be found through the link below.

Local Coverage Determination (LCD): Osteogenesis Stimulators (L33796)

For medical necessity criteria and coding guidance for Medicare Advantage members living outside of Massachusetts, please see the Centers for Medicare and Medicaid Services website for information regarding your specific jurisdiction at https://www.cms.gov.

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products.
See below for situations where prior authorization may be required or may not be required for outpatient services.
Yes indicates that prior authorization is required.
No indicates that prior authorization is not required.
N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO Blue℠</td>
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<td>Medicare PPO Blue℠</td>
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**CPT Codes / HCPCS Codes / ICD Codes**

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following CPT and HCPCS codes are considered not medically necessary for Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity:

**CPT Codes**

<table>
<thead>
<tr>
<th>CPT codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>20979</td>
<td>Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)</td>
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</table>

**HCPCS Codes**

<table>
<thead>
<tr>
<th>HCPCS codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>E0760</td>
<td>Osteogenesis stimulator, low-intensity ultrasound, non-invasive</td>
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</table>

**Description**

**BONE FRACTURES**
An estimated 7.9 million fractures occur annually in the United States. 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 (eg, 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.

Summary
For individuals who have fresh fractures (surgically or nonsurgically managed) who receive LIPUS, the evidence includes randomized controlled trials (RCTs) and a 2017 cumulative meta-analysis of RCTs. 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, 3 low-quality RCTs, and 2 observational studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and quality of life. Reported outcomes in this subgroup of fractures do not include functional outcomes. A wide range of healing rates have been reported across the observational studies with a lack of comparison with routine surgical care, limiting any meaningful interpretation of these results. Additionally, the evidence base on the use of LIPUS in the management of fresh fractures has evolved as described above and there is no demonstrated physiologic mechanism suggesting differential results of LIPUS in fracture nonunion or delayed union. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have stress fractures, osteotomy sites, or distraction osteogenesis who receive LIPUS, 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. Additionally, the evidence base on the use of LIPUS in the management of fresh fractures has evolved as described above and there is no demonstrated physiologic mechanism suggesting differential results of LIPUS in stress fractures, osteotomy sites, or distraction osteogenesis. The evidence is insufficient to determine the effects of the technology on health outcomes.

Policy History
<table>
<thead>
<tr>
<th>Date</th>
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<tr>
<td>Date</td>
<td>Description</td>
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<tr>
<td>2/2018</td>
<td>BCBSA National medical policy review. The following indications were changed from medically necessary to not medically necessary: fresh fractures (surgically and nonsurgically managed) and nonunion/delayed union fractures. Clarified coding information. Effective 2/1/2018.</td>
</tr>
<tr>
<td>10/2016</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>10/2016</td>
<td>Coding information clarified.</td>
</tr>
<tr>
<td>3/2015</td>
<td>New references added from BCBSA National medical policy.</td>
</tr>
<tr>
<td>7/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
</tr>
<tr>
<td>12/2013</td>
<td>Added LCD: L11501 to the policy</td>
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<tr>
<td>2/2013</td>
<td>Ultrasound Accelerated Fracture Healing Device transferred to medical policy 497.</td>
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<tr>
<td>4/2008</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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<tr>
<td>2/2008</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
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**Information Pertaining to All Blue Cross Blue Shield Medical Policies**

Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

**References**


26. Salem KH, Schmelz A. Low-intensity pulsed ultrasound shortens the treatment time in tibial distraction osteogenesis. *Int Orthop.* Jul 2014;38(7):1477-1482. PMID 24390009