FEP Medical Policy Manual

FEP 1.01.05 Ultrasound Accelerated Fracture Healing Device

Effective Date: October 15, 2017

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

Ultrasound Accelerated Fracture Healing Device

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

FDA 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 non-unions, excluding skull and vertebra.

POLICY STATEMENT
Low-intensity pulsed ultrasound may be considered not medically necessary as a treatment of fresh fractures (surgically managed or non-surgically managed).

Low-intensity pulsed ultrasound may be considered not medically necessary as a treatment of fracture Non-union and delayed union fractures.

Low-intensity pulsed ultrasound may be 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 (Heckman et al, 1994; Kristiansen et al, 1997; Emami et al, 1999), but there is variability. For example, 1 study defined fresh as less than 5 days after fracture (Lubbert et al, 2008),
while another defined fresh as up to 10 days post fracture (Mayr et al, 2000). Most fresh closed fractures heal without complications using of standard fracture care (i.e., closed reduction and cast immobilization).

NON-UNION

There is no consensus on the definition of non-unions. 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/non-union (pain, difficulty weight bearing; Buza & Einhorn, 2016). The definition of non-union used in U.S. Food and Drug Administration labeling suggests that non-union is considered established when the fracture site shows no visibly progressive signs of healing, without providing guidance on the timeframe of observation. The following patient selection criteria are consistent with those proposed for electrical stimulation as a treatment of non-unions (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 patient 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

Services, drugs, or supplies that are not medically necessary are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence

For individuals who have fresh fractures (surgically or non-surgically managed) who receive low-intensity pulsed ultrasound (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 non-union or delayed union fracture who receive LIPUS, the evidence includes only lower quality studies including a small systematic review in scaphoid non-unions, 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
FEP 1.01.05 Ultrasound Accelerated Fracture Healing Device

LIPUS in fracture non-union 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

British Medical Journal Rapid Recommendation

The British Medical Journal (BMJ) Rapid Recommendations are a series of articles, produced by BMJ in collaboration with the MAGIC group, to provide clinicians with practice guidelines. In 2017, BMJ Rapid Recommendations published guidelines on the use of low-intensity pulsed ultrasound (LIPUS) for bone healing. The guidelines were based on a 2017 systematic review, which included 26 randomized controlled trials evaluating patients with fresh fractures not surgically managed, fresh fractures surgically managed, non-union fractures, osteotomy, and distraction osteogenesis. The committee concluded that there is “moderate to high certainty evidence to support a strong recommendation against the use of LIPUS for bone healing.” Furthermore, the guideline expert panel discussed whether the results of higher quality studies in patients with fresh fractures reported in Schandelmaier, et al (2017) would apply to other types of fractures including non-unions and osteotomies. “After extensive deliberations, the panel found no compelling anatomical or physiological reasons why LIPUS would probably be beneficial in these other patient populations.”

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES


The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
FEP 1.01.05 Ultrasound Accelerated Fracture Healing Device


POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>March 2012</td>
<td>New</td>
<td>Policy rationale and references updated; arthodesis added to investigational statement; definition of delayed unions revised to 3 months for consistency with definition of nonunion.</td>
</tr>
<tr>
<td>December 2012</td>
<td>Updated Policy</td>
<td>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.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Revised Policy</td>
<td>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.</td>
</tr>
<tr>
<td>March 2015</td>
<td>Updated Policy</td>
<td>Policy updated with literature review; references 11 and 20 added. Information added to Policy Guidelines to clarify definition of “fresh fracture”. Policy statements unchanged.</td>
</tr>
<tr>
<td>December 2016</td>
<td>Updated Policy</td>
<td>Policy updated with literature review through July 1, 2016; references 14 and 16 added. Policy statements unchanged.</td>
</tr>
</tbody>
</table>

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technology. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.