Bone stimulators, electronic and ultrasonic – HealthPartners Care

These services may or may not be covered by your HealthPartners plan. Please see your plan documents for your specific coverage information. If there is a difference between this general information and your plan documents, your plan will be used to determine your coverage.

Administrative process
Prior authorization is required for electronic and ultrasonic bone stimulators.

Authorization for noninvasive bone growth stimulators will be approved up to 3 months rental at a time, unless the device is approved by the FDA only as a single user product (see Table 1 below). Devices approved by the FDA as single user products will be approved as purchases. If authorization for a rental unit is requested beyond the approved 3 months, new x-rays or radiology reports must be submitted.

Coverage
Bone stimulators are generally covered subject to the indications listed below and per your plan documents.

Indications that are covered
For any type of bone stimulator to be covered, all of the following criteria 1-5 must be met:

1. All authorization requests for treatment of nonunion must include serial x-rays which demonstrate that no progressive signs of healing have occurred. (For non-healing spinal fusions, at least 2 x-rays 30 days or more apart are required); AND
2. The member must be compliant with medical treatment, including, but not limited to: any appropriate restrictions on mobility and orders to be non-weight bearing, if necessary; AND
3. The member must be capable of using the bone growth stimulator or has a caregiver capable of using it; AND
4. The device is requested for an FDA approved indication (See Table 1 below); AND
5. None of the conditions listed as contraindications for the requested device are present (See Table 1 below)

Specific criteria for electrical and ultrasonic bone growth stimulators:

1. A non-spinal, noninvasive electrical bone growth stimulator (E0747) is covered for treatment of a fracture nonunion when ALL of the following criteria are met:
   A. At least 3 months have elapsed since the date of fracture; AND
   B. The fracture gap is less than one-half the bone diameter or less than one centimeter; AND
   C. Patient can be adequately immobilized
2. A noninvasive electrical bone growth stimulator (E0747) for congenital pseudoarthroses in the appendicular (non-spinal) skeleton is covered (only if the specific device requested is FDA approved for this indication) when the member can be adequately immobilized.
3. A noninvasive electrical spinal bone growth stimulator (E0748) for treatment of failed spinal fusion is covered when the member has a spinal fusion that has not healed 9 months after the original surgery.
4. A noninvasive (E0748) or invasive (E0749) electrical bone growth stimulator is covered as an adjunct to spinal fusion surgery for patients at high risk of fusion failure when at least one of the following are present:
   A. A history of one or more previous failed spinal fusions; OR
   B. Grade III or worse spondylolisthesis; OR
   C. Scheduled for a multi-level fusion; OR
   D. Is a current smoker; OR
5. A low-intensity ultrasound bone growth stimulator (E0760) is covered for treatment of fracture nonunion when ALL of the following are met:
   - At least 3 months have elapsed since the date of fracture; AND
   - The fracture gap is one centimeter or less; AND
   - Member can be adequately immobilized

6. A low-intensity ultrasound bone growth stimulator (E0760) is covered as an adjunct to conventional treatment of fresh, closed fractures in members who are at high risk of nonunion who meet ALL of the following criteria:
   - History of diabetes, OR recent steroid therapy, OR osteoporosis, OR current smoker OR fracture is associated with extensive soft tissue or vascular damage; AND
   - Member can be adequately immobilized; AND
   - Member is skeletally mature

Table 1

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Device Name and Manufacturer</th>
<th>MHCP covered/FDA Approved Indications</th>
<th>MHCP Non-Covered Indications/Contraindications</th>
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<tbody>
<tr>
<td>E0747</td>
<td>OrthoPak 2 Manufacturer: EBI Medical, Inc.</td>
<td>Established nonunion acquired secondary to trauma *Note: FDA approved as a single user device</td>
<td>Nonunion of vertebrae or flat bones&lt;br&gt;Width of the nonunion is greater than ½ the width of the bone&lt;br&gt;Recipients with synovial pseudarthrosis&lt;br&gt;Recipients who are not skeletally mature (usually not under age 18)&lt;br&gt;Recipients with pacemakers, unless documentation from the cardiologist establishes that use of the bone growth stimulator is safe and appropriate&lt;br&gt;Recipients whose electrical impedance of the tissue between the electrodes will not allow the device to operate within the prescribed 5 to 10 milliamperes range&lt;br&gt;Recipients with nonunion secondary to, or in conjunction with, a pathological condition&lt;br&gt;Recipients who are pregnant or nursing</td>
</tr>
<tr>
<td>E0747</td>
<td>EBI Bone Healing System Model 2001 Manufacturer: EBI Medical, Inc.</td>
<td>Fracture nonunion&lt;br&gt;Failed fusion&lt;br&gt;Congenital pseudarthrosis *Note: FDA approved as a single user device</td>
<td>Fractures of the spine or skull&lt;br&gt;Fracture gaps of more than 1 cm&lt;br&gt;Recipients with synovial pseudarthrosis&lt;br&gt;Recipients with demand pacemakers or implantable defibrillators, unless documentation from the cardiologist establishes that use of the bone growth stimulator is safe and appropriate&lt;br&gt;Recipients who are pregnant&lt;br&gt;Recipients with fixation devices made from magnetic materials</td>
</tr>
<tr>
<td>E0747</td>
<td>OL1000 Manufacturer: di Orthopedics, LLC</td>
<td>Established nonunion acquired secondary to trauma *Note: FDA approved as a single user device</td>
<td>Nonunion of vertebrae or flat bones&lt;br&gt;Recipients with synovial pseudarthrosis&lt;br&gt;Recipients who have demand-type pacemakers, unless documentation from the cardiologist establishes that the use of the bone growth stimulator is safe and appropriate&lt;br&gt;Recipients who have external or internal fixation devices that are constructed</td>
</tr>
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</table>
from magnetic materials
- Recipients who are not skeletally mature (usually not under age 18)
- Recipients who are pregnant or nursing
- Recipients with nonunion secondary to, or in conjunction with, a pathological condition
- Recipients with mental or physical conditions which preclude patient compliance with the physician and device instructions
- Recipients with conditions of atrophy

| E0747 | Physio-Stim | Established nonunion acquired secondary to trauma
*Note: FDA approved as a single user device | Nonunion of vertebrae or flat bones
- Nonunion secondary to, or in connection with, a pathological condition
- Width of the nonunion gap is more than ½ the width of the bone
- Recipients who have synovial pseudarthrosis
- Recipients who are not skeletally mature (usually not under age 18)
- Recipients who have a demand-type pacemaker when the bone growth stimulator will be placed in close proximity to the pacemaker. If a recipient has a pacemaker, documentation from a cardiologist is required.

| E0748 | Spinal-Stim | Adjunct to spinal fusion
- Salvage of failed spinal fusion
*Note: FDA approved as a single user device | Recipients who have an implanted cardiac pacemaker
- Recipients who are pregnant or nursing
- Recipients not skeletally mature (usually not under age 18)
- Recipients with mental or physical conditions which preclude compliance with physician and device instructions
- Recipients with osseous or ligamentous spinal trauma, Paget’s disease, moderate to severe osteoporosis, metastatic cancer, renal disease or uncontrolled diabetes mellitus

| E0748 | SpinalPak II | Adjunct to primary spinal fusion for one or two levels
*Note: FDA approved as a single user device | Recipients who have cardiac pacemakers or cardioverters, unless documentation from the cardiologist establishes that use of the bone growth stimulator is safe and appropriate
- Recipients who are pregnant or intending to become pregnant
- Recipients with spondylitis, infection, Paget’s disease, osteoporosis, cancer, renal disease, diabetes mellitus or trauma of the lumbar spine

| E0748 | SpinaLogic | Adjunct to primary lumbar spinal fusion surgery for one or two levels
*Note: FDA approved as a single user device | Recipients with demand-type pacemakers or implantable cardioverter defibrillators
- Recipients who are pregnant
- Recipients who are not skeletally mature (usually not under age 18)
- Recipients with osseous or ligamentous spinal trauma, spondylitis, Paget’s disease, severe osteoporosis, metastatic cancer, renal disease, or uncontrolled diabetes mellitus
- Recipients with mental or physical conditions which preclude patient compliance with the physician and device instructions
- Recipients who are unable to abstain from smoking during treatment periods
<table>
<thead>
<tr>
<th>E0760</th>
<th>Exogen 4000+</th>
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<td>Manufacturer: Smith &amp; Nephew</td>
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</table>

- Established nonunions excluding skull and vertebra
- Fresh, closed, posteriorly displaced distal radius fractures
- Fresh, closed tibial diaphysis fractures
*Note: FDA approved as a single user device

| Nonunion fracture of skull or vertebra |
| Fresh fractures other than the distal radius or tibial diaphysis |
| Fresh fractures with post-reduction displacement of more than 50% |
| Fresh fractures due to bone pathology or malignancy |
| Recipients who are not skeletally mature (usually not under age 18) |
| Recipients who are pregnant or nursing |
| Recipients who have active, implantable devices such as cardiac pacemakers, unless documentation from the cardiologist established that use of the bone growth stimulator is safe and appropriate |
| Recipients with thrombophlebitis, vascular insufficiency, abnormal skin sensitivity, sensory paralysis, alcoholism and/or nutritional deficiency |
| Recipients receiving steroid, anti-coagulant, prescription non-steroidal anti-inflammatory, calcium channel blocker and/or diphosphonate therapy |

**Indications that are not covered**

1. Noninvasive or invasive electrical bone growth stimulators are considered investigative for treatment of a fresh fracture.
2. Noninvasive or invasive electrical bone growth stimulators and low-intensity ultrasound bone growth stimulators are considered investigative for treatment of delayed (as opposed to stalled) union fracture.
3. Invasive bone growth stimulators are considered investigative for any indication other than as an adjunct to spinal fusion.
4. Low-intensity ultrasound bone growth stimulators for treatment of congenital pseudoarthroses are not FDA approved and are considered investigative.
5. Low-intensity bone growth stimulators are considered investigative for treatment of open fractures.
6. Low-intensity ultrasound bone growth stimulators are not considered a medically appropriate treatment for patients with fresh fractures who do not have the risk factors specified above (6a-c).
7. Bone growth stimulators are not covered for recipients who have any contraindication listed in the device’s package insert (see Table 1).
8. Bone growth stimulators are not covered for any indication for which the specific stimulator has not been approved by the Food and Drug Administration (See Table 1).

**Definitions**

**Electrical stimulation** to augment bone repair can be attained either invasively or noninvasively. Invasive devices provide electrical stimulation directly at the fracture site either through percutaneously placed cathodes or by implantation of a coiled cathode wire into the fracture site. The power pack for the latter device is implanted into soft tissue near the fracture site and subcutaneously connected to the cathode, creating a self-contained system with no external components. The power supply for the former device is externally placed and the leads connected to the inserted cathodes. With the noninvasive device, opposing pads, wired to an external power supply, are placed over the cast. An electromagnetic field is created between the pads at the fracture site.

**An ultrasonic osteogenic stimulator** is a non-invasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, conductive gel in order to stimulate fracture healing.

**Codes**
If available, codes are listed below for informational purposes only, and do not guarantee member coverage or provider reimbursement. The list may not be all-inclusive.

- E0747 - osteogenesis stimulator, electrical, noninvasive, other than spinal application
- E0748 - osteogenesis stimulator, electrical, noninvasive, spinal applications
- E0749 - osteogenesis stimulator, electrical, surgically implanted
- E0760 - osteogenesis stimulator, low intensity ultrasound

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Portions of the contents of these coverage criteria relating to Minnesota Public Programs medical coverage criteria are taken directly from the Minnesota Health Care Programs Provider Manual, Bone Growth Stimulators 5/6/2014: http://www.dhs.state.mn.us/main/idcplg?IdcService=GET_DYNAMIC_CONVERSION&RevisionSelectionMethod=LatestReleased&dDocName=dhs16_149902

**Products**

This information is for most, but not all, HealthPartners plans. Please read your plan documents to see if your plan has limits or will not cover some items. If there is a difference between this general information and your plan documents, your plan documents will be used to determine your coverage. These coverage criteria may not apply to Medicare Products if Medicare requires different coverage. For more information regarding Medicare coverage criteria or for a copy of a Medicare coverage policy, contact Member Services at 952-883-7979 or 1-800-233-9645.

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