Bone Growth Stimulators

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INSTRUCTIONS FOR USE: Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Company reserves the right to determine the application of medical policies and make revisions to medical policies at any time. The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement. Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

SCOPE: Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as “Company” and collectively as “Companies”).

PLAN PRODUCT AND BENEFIT APPLICATION

☒ **Commercial** ☒ **Medicaid/OHP*** ☐ **Medicare****

*Medicaid/OHP Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

**Medicare Members

This *Company* policy may be applied to Medicare Plan members only when directed by a separate *Medicare* policy. Note that investigational services are considered **"not medically necessary"** for Medicare members.

COVERAGE CRITERIA

Note: Please see the Policy Guideline section below for definitions of failed spinal fusion, fracture nonunion, spondylolisthesis, and appendicular skeleton.

Spinal Electrical Bone Growth Stimulator

Invasive Stimulator

I. The use of invasive spinal electrical bone growth stimulation as an adjunct to lumbar spinal fusion may be considered **medically necessary** for patients who have at **least one** of the following (A.-C.) high risk factors for fusion failure:

   A. Previously failed spinal fusion(s); **or**
   B. Spinal fusion to be performed at more than one level; **or**
   C. Grade III or worse spondylolisthesis;

II. The use of invasive spinal electrical bone growth stimulation is considered **not medically necessary and is not covered** when criterion I. above is not met, including, but not limited to, as an adjunct to cervical spinal fusion.

Noninvasive Stimulator

III. The use of noninvasive spinal electrical bone growth stimulation as an adjunct to lumbar spinal fusion may be considered **medically necessary** for patients who have **at least one** of the following (A.-C.) high risk factors for fusion failure:

   A. Previously failed fusion(s); **or**

B. Fusion to be performed at more than one level; **or**
C. Grade III or worse spondylolisthesis;

IV. The use of noninvasive spinal electrical bone growth stimulation is considered **not medically necessary and not covered** when criterion III. above is not met, including, but not limited to, as an adjunct to cervical spinal fusion.

V. The use of noninvasive spinal electrical bone growth stimulation for the treatment of failed lumbar or cervical spinal fusion may be considered **medically necessary** when **both** of the following (A.-B.) criteria are met:

A. **At least** 6 months have passed since the fusion surgery; **and**
B. Serial (minimum of two) radiographs confirm there is no evidence of healing for **at least** 3 months.

VI. The use of noninvasive spinal electrical bone growth stimulation is considered **not medically necessary and is not covered** when criterion V. above is not met.

Non-Spinal Electrical Bone Growth Stimulator

Noninvasive Stimulator

VII. The use of noninvasive, non-spinal electrical bone growth stimulation may be considered **medically necessary** for the treatment of nonunion fractures or congenital pseudoarthroses when **all** of the following (A.-D.) criteria are met:

A. Long or short bone of the appendicular skeleton to be treated; **and**
B. **At least** 3 months have passed since:
    a. The date of fracture if treated conservatively (non-surgical); or
    b. The date of non-fusion surgical treatment of the fracture; **and**
C. Serial (minimum of two) radiographs confirm there is no evidence of healing for **at least** 3 months; **and**
D. The fracture gap is 1 cm or less.

VIII. The use of noninvasive, non-spinal electrical bone growth stimulation is considered **not medically necessary and is not covered** when criterion VII. above is not met, including, but not limited to, the following:

A. Delayed union fractures (less than 3 months have passed since the date of fracture or date of non-fusion surgical treatment of the fracture)
B. Fresh fractures
C. As an **adjunct** to fusion
D. For the treatment of a **failed** fusion and/or fracture in the immediate post-operative period
E. As an **adjunct** to fusion or for the treatment of a **failed** fusion for indications other than fracture (e.g., osteoarthritis)
F. Osteonecrosis (Avascular necrosis of bone)

Invasive Stimulator

IX. The use of invasive non-spinal electrical bone growth stimulation for non-spinal conditions, including fracture nonunion and congenital pseudoarthroses, is considered **investigational and is not covered**.

Ultrasound Bone Growth Stimulator

X. The use of ultrasound bone growth stimulation may be considered **medically necessary** for the treatment of a nonunion fracture (traumatic, non-osteoporotic, not tumor related) when **all** of the following (A.-D.) criteria are met:

   A. Long or short bone of the appendicular skeleton to be treated; **and**
   B. **At least** 3 months have passed since the date of fracture or date of surgical treatment of the fracture; **and**
   C. Serial radiographs (minimum of two) confirm there is no evidence of healing for **at least** 3 months; **and**
   D. The fracture gap is 1 cm or less.

XI. The use of ultrasound bone growth stimulation is considered **not medically necessary and is not covered** when criterion X. and XI. above are not met, including, but not limited to, the following:

   A. Fresh fractures (other than Zone 2 fractures of the 5th metatarsal (i.e., Jones fracture))
   B. Stress fractures
   C. Delayed union fractures (less than 3 months have passed since the date of fracture or date of non-fusion surgical treatment of the fracture)
   D. Distraction osteogenesis of the lower leg
   E. Osteotomy of the forearm
   F. As an adjunct to surgically treated fractures that did not respond to conservative care (must meet criterion X. B.)
   G. Non-union of a surgical arthrodesis

Link to Evidence Summary

POLICY CROSS REFERENCES

None

The full Company portfolio of current Medical Policies is available online and can be accessed here.

POLICY GUIDELINES

DOCUMENTATION REQUIREMENTS

In order to determine the medical necessity of the request, the following documentation must be provided at the time of the request. Medical records to include documentation of all of the following:

- Imaging report, which must be submitted for medical necessity review;
- All medical records and chart notes pertinent to the request. This includes:
    - History
    - Physical examination
    - Treatment plan

DEFINITIONS

- Failed spinal fusion is defined as fusion which has not healed and a minimum of 6 months have elapsed since original surgery, as evidenced by serial x-rays over the course of the last 3 months prior to the request.
- Fracture nonunion is defined as a decelerating healing process as determined by serial x-rays, together with a lack of clinical and radiological evidence of union, bony continuity, or bone reaction at the fracture site for no less than 3 months from the initial injury or treatment.
- The appendicular skeleton includes 126 bones of the pectoral girdles, the upper limbs, the pelvic girdle, and the lower limbs.
    - Pectoral girdles
        - Clavicle (2)
        - Scapula (2)
    - Upper extremity
        - Humerus (2)
        - Radius (2)
        - Ulna (2)
        - Carpals (16)
        - Metacarpals (10)
        - Phalanges (28)
    - Pelvic girdle
        - Coxal, innominate, or hip bones (2)
    - Lower extremity
        - Femur (2)
        - Tibia (2)
        - Fibula (2)
        - Patella (2)
        - Tarsals (14)
        - Metatarsals (10)
        - Phalanges (28)
- The American Academy of Orthopedic Surgeons (AAOS) defines spondylolisthesis the slippage of a vertebra forward and out of place.[1] This can occur anywhere along the spine, but is most common in the lumbar spine. Spondylolisthesis is graded as follows:

Grade	% of Vertebral Slippage
Grade I	25%
Grade II	50%
Grade III	75%
Grade IV	100%
Grade V	Complete slippage (i.e., spondyloptosis)

BACKGROUND

Bone Non-fusion or Non-Union

Bone growth of healthy, solid bone is required after fracture or arthrodesis (joint fusion surgery); however, this does not always occur. Delayed union or nonunion fractures are fractures that do not heal completely within an expected duration. Pseudoarthrosis (bone fusion failure) occurs following arthrodesis, and commonly leads to spinal fusion failure. Risk factors for poor or inadequate bone healing include fracture type, tobacco use, alcoholism, diabetes, older age, medications (e.g., steroids), metabolic diseases, and inadequate fracture treatment.

Fifth Metatarsal Fractures

There are three main types of fifth metatarsal fracture.2 Zone 1 fractures (i.e. Avulsion or "Pseudo-Jones" fractures) occur at the proximal tubercle and are caused when bony fragment is detached by ligament or other connective tissue. Zone 2 fractures (i.e. Jones fracture) occur at the metaphyseal-diaphyseal junction and are at high risk for non-union due to the interruption of the bloody supply at the avascular (watershed) zone. Zone 3 fractures (i.e. stress fractures) occur at the proximal diaphysis and are associated with cavovarus foot deformities or sensory neuropathies.

Invasive Electrical Bone Growth Stimulator (EBGS)

According to Hayes, invasive EBGS, "are devices intended to stimulate growth of bone for fracture healing and other conditions such as arthrodesis."3 The invasive EBGS consists of a generator, which produces constant electrical current using a battery and electronic circuit. The generator is connected to leads which attach to 1 or 2 cathodes placed at the bone site needing fusion or growth. All of these device components are surgically implanted within the body.

Noninvasive Electrical Bone Growth Stimulator (EBGS)

Noninvasive EBGS devices, "deliver current to the surgical site using technologies such as direct current electrical stimulation (DCES), capacitive coupling electric field (CCEF), pulsed electromagnetic fields (PEMF), and combined magnetic fields (CMF)."4,5 The device consists of a controller and an external treatment unit or electrodes. The treatment unit or electrodes are worn for a prescribed regimen, typically several hours a day for no more than 270 days.

Ultrasound (US) Bone Growth Stimulator (USBGS)

According to Hayes, "(u)ltrasound (US) bone growth stimulators deliver mechanical stimulation to the fracture site through the application of low-intensity, pulsed, high-frequency pressure waves."6 Low intensity pulsed ultrasound (LIPUS) transmits mechanical pressure waves through the skin and soft tissue to accelerate the bone healing and repair process. "This device generally consists of: (1) a main operating unit, powered by a lithium battery; and (2) a transducer, powered by the main operating unit battery supply, which supplies the US signal to the skin at the fracture site." The USBGS can be applied to the fracture site within, on, or without a cast. For in and on cast, the device is, "contained in a retaining and alignment fixture that allows the entire device to be attached to the fracture site."6 For no cast application, the device is contained within a strap assembly.

REGULATORY STATUS

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Approval or clearance by the Food and Drug Administration (FDA) does not in itself establish medical necessity or serve as a basis for coverage. Therefore, this section is provided for informational purposes only.

Noninvasive Electrical Bone Growth Stimulators

Several noninvasive electrical bone growth stimulators have been approved under the FDA premarket approval (PMA) process. This may not be an all-inclusive list. FDA-approved devices can be found by searching product code LOF in the FDA PMA database.

Device & Manufacturer	Indications for Use	Contraindications for Use
Biomet Orthopak Noninvasive Bone Growth Stimulator System by Zimmer Biomet[2]	Treatment of established nonunion fractures acquired secondary to trauma, excluding vertebrae and all flat bones, where width of nonunion defect is less than half the width of bone to be treated.	Synovial pseudarthrosis
EBI Bone Healing System by Zimmer Biomet[3]	Treatment of fracture nonunions, failed fusions, and congenital pseudarthrosis in the appendicular system.	• Not recommended for patients with certain types of pacemakers or implantable defibrillators • Pregnant patients • Nonunion fractures with synovial pseudarthrosis (fluid filled gap)

Physio-Stim by Orthofix[4]	Treatment of established nonunion fractures acquired secondary to trauma, excluding vertebrae and all flat bones, where width of nonunion defect is less than half the width of bone to be treated.	Synovial pseudarthrosis
Cervical-Stim Osteogenesis Stimulator by Orthofix[5]	As an adjunct to cervical fusion surgery in patients at high risk for nonfusion.	• No known contraindications. • Warning that should not be used in patients with cardiac pacemaker or ICD; device should be removed prior to any imaging procedure.
SpinaLogic by DJO Global Inc.[6]	As an adjunctive electromagnetic treatment to primary lumbar spinal fusion surgery for 1 or 2 levels.	• Contraindicated in patients with demand-type pacemakers, ICD, pregnancy. • Warning that safety and effectiveness in individuals lacking skeletal maturity have not been established.
SpinalPak by Zimmer Biomet Inc.[7]	As an adjunctive electrical treatment to primary lumbar spinal fusion surgery for 1 or 2 levels.	• Concomitant use of device and pacemaker or ICD must be assessed on individual basis prior to use; patient should be referred to cardiologist for monitoring of pacemaker function while wearing active device; if adverse changes in pacemaker rhythm or input, device should not be used. • Safety and effectiveness not studied in pregnancy.
Spinal-Stim Osteogenesis Stimulator by Orthofix Inc.[8]	As an adjunct to spinal fusion to increase probability of fusion success and as nonoperative treatment of salvage failed spinal fusion when ≥9 months passed since last surgery.	• Contraindicated in patients with cardiac pacemaker or ICD. • Safety during pregnancy and breastfeeding not established.

Invasive Electrical Bone Growth Stimulators

Several invasive electrical bone growth stimulators have been approved under the FDA premarket approval (PMA) process. This may not be an all-inclusive list. FDA-approved devices can be found by searching product code LOE in the FDA PMA database.

Device & Manufacturer	Indications for Use	Contraindications for Use
EBI SPF Implantable Spinal Fusion Stimulator by EBI, LLC[9]	Not reported on FDA website.	Not reported on FDA website.
Osteostim by EBI, LLC[10]	Not reported on FDA website.	Not reported on FDA website.
24R Direct Current Bone Growth Stimulator by Zimmer Inc.[11]	Not reported on FDA website.	Not reported on FDA website.

Ultrasound Bone Growth Stimulators

Only one ultrasound bone growth stimulator has been approved under the FDA premarket approval (PMA) process. The FDA created a separate classification for ultrasound bone growth stimulators: LPQ.

Device & Manufacturer	Indications for Use	Contraindications for Use
EXOGEN 4000+™ Ultrasound Bone Healing System by Smith & Nephew, Inc.[12,13]	• The non-invasive treatment of established non-unions† excluding skull and vertebra. • Accelerating the time to a healed fracture for fresh, closed, posteriorly displaced distal radius 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. †A non-union is considered to be established when the fracture site shows no visibly progressive signs of healing.	No known contraindications

CLINICAL EVIDENCE AND LITERATURE REVIEW

EVIDENCE REVIEW

Invasive Electrical Bone Growth Stimulation

In 2016 (updated in 2020), Hayes conducted an evidence review to evaluate invasive electrical stimulation (IES) for adjunctive use in arthrodesis or delayed union or nonunion fractures.[14] The review identified eleven studies as eligible for inclusion, encompassing 3 randomized controlled trials (RCTs), 3 comparative cohort studies, and 5 case series. The studies evaluated adult patients undergoing spinal arthrodesis (5 studies lumbar, 1 study cervical), foot and/or ankle arthrodesis (2 studies), and delayed or nonunion fractures (3 studies). Sample sizes ranged from 10 to 143 participants per study, and follow-up durations were from 6 months to 10 years. The primary outcome of interest for all studies was rates of arthrodesis or bone healing.

In the evaluation of arthrodesis of the lumbar spine, one RCT reported statistically significantly higher rates of fusion or bone union with IES than with no stimulation (81% versus 54%). However, 2 other RCTs did not find greater rates of arthrodesis or bone union with IES. In regards to the other indications for IES, "(s)mall, very-poor-quality uncontrolled studies reported that fusion or bone union rates for other indications were 94% for arthrodesis of cervical spine (1 study), 65% to 86% for arthrodesis of foot and ankle (2 studies), and 80% to 86% for delayed or nonunion fractures (3 studies)."[15] Complications related to IES included irritation at device implantation site and cathode wire breakage. These events occurred at low rates and were not related to any serious or severe adverse reactions.

The quality of included studies was influenced by lack of outcome assessor blinding, lack of use of validated or widely accepted outcome measures, and excessive loss to follow-up (>15%). Ultimately, Hayes concluded the following ratings for IES:

- C (potential but unproven benefit)—For invasive electrical stimulation (IES) as an adjunct to lumbar spinal arthrodesis in adult patients considered to be at high risk of pseudarthrosis due to factors such as previously failed spinal fusion at the same site or multilevel fusion. This Rating reflects inconsistency in the available low-quality body of evidence. Some older evidence (1 randomized controlled trial [RCT], 1 comparative cohort study) suggests that IES as an adjunct to lumbar spinal arthrodesis may offer benefit to patients at high risk for pseudarthrosis. However, findings from 2 newer, higher-quality RCTs suggest no benefit. No serious safety issues arose with use of IES. Future evidence may warrant downgrading IES to a D1 Hayes Rating.
- D2 (insufficient evidence) —For IES for all other indications. This Rating reflects the very-low-quality evidence and/or the paucity of evidence evaluating IES in these patient populations.[14]

Nonrandomized Studies

In 2018, Coric and colleagues conducted a retrospective cohort study evaluating pulsed electromagnetic field (PEMF) stimulation for the treatment of cervical arthrodesis in high-risk populations.[16] To this end, investigators compared fusion rates between patients receiving PEMF stimulation (n=274) and, via *post hoc* analysis, 160 high-risk patients receiving PEMF stimulation during a pivotal RCT from 2014. Fisher's exact test and multivariate logistic regression was used to compare fusion rates between PEMF-treated subjects and historical controls. Investigators reported that OEMP significantly increased the fusion rate at 12 months for subjects with at least one clinical risk factor (i.e. advanced age, nicotine use, osteoporosis, diabetes). Limitations included the study's retrospective design and lack of prospective controls. Investigators concluded that PEMF stimulation may be an effective adjunct for cervical

arthrodesis in high-risk populations, yet called for additional, higher powered studies to both confirm these findings and to assess the efficacy of PEMF stimulations on other patient populations.

Noninvasive Electrical Bone Growth Stimulation

- In 2016 (reviewed 2021), Hayes conducted an evidence review to assess noninvasive electrical bone growth stimulators (EBGS) for spinal fusion or foot and ankle indications.[17] The review identified 8 randomized controlled trials (RCTs) as eligible for inclusion. Of these RCTs, 4 (fair quality) evaluated patients undergoing lumbar spinal fusion, 1 (fair quality) evaluated patients undergoing cervical spinal fusion, and 3 (1 good quality, 1 fair quality, and 1 poor quality) evaluated patients undergoing arthrodesis for ankle or foot indications. The sample sizes ranged from 30 to 323 patients with follow-up times varying from 7 months to 2 years. The outcome measures included radiographic fusion rate, overall radiographic and clinical success, time to radiographic joint union, pain, return to normal activities, and complications.

A total of 3 RCTs showed some significant positive clinical benefit in radiographic and/or clinical success rates with EBGS after lumbar spinal fusion. Radiographic fusion rates ranged from 64% to 91% for EBGS compared to 43% to 82% for placebo therapy. One RCT showed no significant benefit of EBGS following lumbar spinal fusion. In the one RCT evaluating electrical stimulation following cervical spinal fusion, EBGS promoted fusion at 6 months compared to placebo (83.6% versus 68.6%). However, EBGS did not improve cervical fusion at 12 months, pain, health status, or function. In regards to foot or ankle arthrodesis, "(i)n a single-blind RCT, EBGS versus no EBGS shortened the time to radiographic union in patients who had undergone primary talonavicular fusion (12.2 versus 17.6 weeks) and calcaneocuboid fusion (13.1 versus 17.7 weeks), but had no effect in patients who had undergone subtalar fusion (12.9 versus 14.5 weeks)."[17] Furthermore, patients undergoing subtalar fusion had 100% success rates in both the EBGS and placebo groups; whilst patients undergoing calcaneocuboid fusion who were in the placebo group had higher success rates than patients in the EBGS group (95% versus 89%). The included studies indicated that EBGS is safe, and no major adverse events related to the device or treatments were reported.

The quality of included studies was influenced by small sample size, no power analysis, no intention-to-treat (ITT) analysis, high attrition rates, and inadequate follow-up times. Ultimately, Hayes concluded the following ratings:

  - B (some proven benefit) —For noninvasive EBGS as an adjunct to standard lumbar or lumbosacral spinal fusion in adult patients at high risk for failed fusion.
  - C (potential but unproven benefit) —For noninvasive EBGS as an adjunct to standard lumbar or lumbosacral spinal fusion in adult patients who are not at high risk for failed fusion.
  - C (potential but unproven benefit)—For noninvasive EBGS as an adjunct to standard cervical spinal fusion in adult patients at high risk for failed fusion.
  - C (potential but unproven benefit) —For noninvasive EBGS as an adjunct to standard foot or ankle arthrodesis in adult patients. [17]

- In 2016 (reviewed 2020), Hayes conducted an evidence review to evaluate noninvasive electrical bone growth stimulators (EBGS) for acute, delayed union, and nonunion fractures.[18] The review

identified 13 randomized controlled trials (RCTs) as eligible for inclusion. "Eight RCTs (2 good quality, 4 fair quality, 2 poor quality) were in patients with fresh fractures (< 14 days) and 5 RCTs (3 fair quality, 2 poor quality) were in patients with delayed union or nonunion fractures."[18] Sample sizes ranged from 16 to 218 patients and follow-up durations varied from 4 weeks to 48 weeks. The outcome measures included clinical union, radiographic fracture union, pain, functional activity.

In regards to fresh fractures, one RCT showed a significant positive benefit in time to fracture healing and pain with EBGS compared to placebo. Two other RCTs (poor quality) evaluating fresh fractures also showed a significant improvement with active EBGS over placebo. Both RCTs assessing patients with delayed union fractures found a statistically significant positive benefit for union rates with EBGS (25% to 77.4%) compared to placebo (4% to 48.1%). Two of the three RCTs evaluating EBGS in patients with nonunion fractures found a statistically significant positive benefit for union rates with EBGS (60% to 89%) versus placebo (0% to 50%). The included studies also indicated that EBGS is very safe, as no studies reported safety concerns.

The quality of included studies was influenced by small sample size, no predefined primary endpoint(s), no power analysis, no intention-to-treat (ITT) analysis, underpowered due to poor enrollment, high dropout, and poor treatment adherence. Ultimately, Hayes concluded the following ratings for noninvasive EBGS for delayed union and nonunion fractures:

- B (some proven benefit) —For noninvasive EBGS devices as an adjunct to conventional treatment for nonunion fractures of the tibia and other long bones in adults. This Rating reflects a low-quality body of evidence demonstrating improved fracture healing outcomes compared with placebo devices and no concerns regarding safety, as well as the expectation that a nonunion fracture will not heal without further intervention.
- C (potential but unproven benefit) —For noninvasive EBGS devices as an adjunct to conventional treatment for delayed union fractures of the tibia or other long bones in adults. This Rating reflects a low-quality body of evidence demonstrating improved fracture healing outcomes compared with placebo devices, and no concerns regarding safety.
- D1 (no proven benefit) —For noninvasive EBGS devices as an adjunct to conventional treatment for fresh fractures in adults. This Rating reflects a moderate-quality body of evidence showing no benefit compared with placebo or no device in the healing of newly acquired fractures of the extra-articular distal radius, femoral neck, scaphoid, and tibia. Noninvasive EBGS does not pose any safety concerns in this patient population.[18]

- A systematic review and meta-analysis was published in 2020 on the efficacy of electrical stimulation for spinal fusion.[19] Akhter and colleagues found 7 eligible randomized trials that compared efficacy of postoperative electrical stimulation to no stimulation or placebo in promoting radiographic fusion in patients undergoing spinal fusion. Two independent reviewers screened publications for inclusion, and studies that were not randomized and had less than one year follow up were excluded. There were a total of 941 patients in the meta-analysis, 487 who received postoperative electrical stimulation. Six studies analyzed lumbar fusion and one study analyzed cervical fusion. Four studies investigated non-invasive stimulation, two studies investigated invasive stimulation, and one study investigated both in comparison to control. The analysis found that

electric stimulation increased odds of successful fusion by 2.5 times relative to control (OR=2.53; 95 CI%, 1.86-3.43, p<0.00001). Smokers benefited slightly more than nonsmokers, and single level fusion benefited slightly more than multi-level fusion, although not significantly so for either. Noninvasive techniques had similar results compared to invasive. Capacitive coupling (noninvasive) had and odds ratio of 3.00, compared to direct current (invasive)'s odd ratio of 2.88, and pulsed electromagnetic fields' (noninvasive) 2.59. The authors concluded that they "found moderate-level evidence supporting the use of postoperative electrical stimulation as an adjunct to spinal fusion surgery."

- In 2021, ECRI published a clinical evidence assessment of Cervical-Stim Electrical Bone Growth Stimulation (Orthofix Medical, Inc.) for facilitating healing after cervical fusion. The review included one randomized trial (n=323) and one retrospective comparative study (n=274). The Cervical-Stim pivotal RCT by Foley and colleagues compared electrical stimulation as an adjunct to anterior cervical discectomy and fusion, versus discectomy and fusion alone. At 6 months postoperatively, the electrical stimulation group had a significantly higher fusion rate compared to the control group (83.6% vs 68.6%; p=0.0065). At 12 month, fusion rates were no longer significantly different. No differences were found in VAS scores, neck disability index, and SF-12 scores. The retrospective study used a historical control and found improved fusion rates at both 6 and 12 months.

ECRI found a number of limitations among the 2 studies, including:

- The RCT was lacking blinding and therefore at high risk of bias
- The retrospective study used pos hoc subgroup analysis, high risk of confounding effects
- Both studies used the same patients as the control group, limiting the generalizability of the results.

ECRI concluded that the current evidence evaluating Cervical-Stim is inconclusive due to the very low quality of the evidence.

Osteonecrosis (Avascular necrosis of bone)

In 2018, Al-Jabri and colleagues conducted a systematic review evaluating the role of electrical stimulation in the management of avascular necrosis of the femoral head in adults.[20] Independent investigators systematically searched the literature through April 2016, identified eligible studies, assessed study quality and extracted data. In total, 10 studies were included for review (8 prospective and 2 retrospective studies. In 6 studies, electrical stimulation was evaluated as an adjunct to other treatments (e.g. core decompression and bone grafting). One of these studies showed improvement in patients' Harris Hip scores and roetgeneographic progression, although the percentage of patients needing total hip arthroplasty was the same across both groups. Another study showed that patients receiving stimulation eventually required more total hip arthroplasties despite comparative improvements in radiological and clinical outcomes. Investigators concluded that while pulsed electromagnetic fields may improve the management of early avascular necrosis, additional large, high-quality studies evaluating stimulation, both alone and alongside other treatments, were necessary to confirm treatment efficacy.

Ultrasound Bone Growth Stimulation

Fracture Nonunions and Fresh Fractures

- In 2017, Lou and colleagues published a meta-analysis on the effects of low-intensity pulsed ultrasound (LIPUS) on fresh fractures.[21] Studies included quasi-randomized and randomized controlled studies from Jan 1980 to Nov 2016. Twelve trials were included in the analysis, totalling 1099 patients. Sample sizes ranged from 20 to 601 patients. One included trial only offered an abstract, one trials did not report randomization technique (quasi-randomized), and 10 trials were RCTs. Only 2 trials had low risk of reporting bias because most trials did not publish protocols. Pooled results of 11 trials that reported time to fracture union showed that LIPUS significantly reduced time to fracture union compared to placebo groups (Standard mean difference: -0.65; P, 0.01). LIPUS also improved quality of life compared to placebo (P=0.02). Eight trials provided data on incident of delayed union and nonunion, and results showed that LIPUS did not reduce incident compared to placebo (risk reduction: 1.02; P= 0.94).

This systematic review had a number of limitations, including:

- Inadequate concealment of treatment allocation,
- High loss to follow up
- Small sample sizes for most included studies
- Heterogeneity in treatment, participants, and study protocol

The authors concluded that LIPUS may reduce time to fracture union and improve quality of life, but does not have an effect on functional recovery and incident of delayed union or nonunions. They state that LIPUS may be a good treatment for adults with fresh fractures, but further high level research is needed to determine the clinical circumstances under which LIPUS is valid and the optimal use of this therapy.

- In 2015 (archived 2020), Hayes conducted an evidence review to evaluate ultrasound (US) bone growth stimulation as an adjunct to conventional bone fracture care.[22] The review identified 20 randomized controlled trials (RCTs) and 6 nonrandomized studies as eligible for inclusion. The sample sizes ranged from 16 to 101 patients for the RCTs and 60 to 1317 patients for the nonrandomized studies. Follow-up durations varied from 1 week to 6 years, and the outcome measures of interest included time to radiological and clinical healing, return to activities, pain, joint function, range of motion, quality of life, and complications.

The findings of the evidence review indicated that “US therapy for bone growth stimulation is effective as an adjunct to conventional management for treatment of nonunions in skeletally mature patients.” The 6 RCTs evaluating nonunion fractures provided consistent evidence that US stimulation is an effective treatment for these fractures that respond poorly to surgical treatment. The 3 RCTs evaluating US stimulation for treatment of fresh fractures of the radius and scaphoid provided inconsistent evidence that US stimulation improves fresh fracture healing. These 3 RCTs all reported reduced healing time with US stimulation; however, no positive impact was reported for pain, health status, or health outcomes. Only one of the RCTs “found that US treatment was associated with a statistically significant 8% increase in mean final bone density, which supports the conclusion that US treatment is promoting

solid fusion rather than more rapid but less substantial bone healing." In regards to fresh tibial diaphyseal fractures, the evidence was again inconsistent to support that US improves fresh fracture healing. Two of six RCTs found that US therapy provided statistically significant improvements in fracture healing; however, US therapy was not associated with any significant improvement sin radiological measurement.

The overall quality of evidence was influenced by "small sample size, incomplete reporting of patient demographics, no blinding of assessment to treatment, absence of placebo treatment of the control group, indirect assessment of fracture healing, ending assessment of healing before most fractures were completely healed, no assessment of functional outcomes, inadequate statistical analysis, and brief or no follow-up after US therapy ended." Ultimately, Hayes concluded the following ratings for the use of US bone growth stimulation for nonunions and fresh fractures:

- B (some proven benefit)—For ultrasound (US) therapy as an adjunct to conventional treatment for nonunions other than the skull or vertebrae in skeletally mature patients, and excluding those that are related to malignancy, given that there is documentation that healing has ceased or is not progressing.
- C (potential but unproven benefit)—For US therapy as an adjunct to conventional treatment for fresh fractures. This Rating reflects inconsistent evidence of benefit from a large number of RCTs for this indication.
- C (potential but unproven benefit) – For US therapy as an adjunct to conventional treatment for distraction osteogenesis of the lower leg or osteotomy of the forearm. This Rating reflects inconsistent evidence of benefit from RCTs for this indication.
- C (potential but unproven benefit) – For US therapy as an adjunct to conventional treatment for delayed unions. This Rating reflects a small amount of evidence that provides partial support for US therapy as treatment for delayed unions.
- D2 (insufficient evidence) – For US therapy for the following indications: skeletal immaturity; pregnant or nursing women; patients receiving medications that may interfere with bone metabolism, including steroids, anticoagulants, and prescription nonsteroidal anti-inflammatories, bisphosphonate therapies, or calcium channel blockers; presence of vascular insufficiency, thrombophlebitis, sensory paralysis, abnormal skin sensitivity, nutritional deficiency, and/or alcoholism; fresh, open grade II or III, or unstable fractures; fractures with postreduction displacements of more than 50%; pathological fractures or those associated with malignancy; nonunions of the skull or vertebrae; and fresh fractures that require surgical intervention, or internal or external fixation. This Rating reflects the paucity of evidence regarding the efficacy and safety of US therapy for these indications.[22]

- In 2014, Cochrane conducted a systematic review evaluating the efficacy of low-intensity ultrasound (LIPUS), high-intensity ultrasound (HIFUS) and extracorporeal shockwave therapies (ECSW) for the treatment of acute fractures in adults.[23] Independent investigators searched the literature through June 2014, identified eligible studies, assessed study quality and extracted data. In total, 12 studies were included for review (8 randomized placebo-controlled trials; 2 RCTs without placebo controls, 1 quasi-randomized placebo-controlled trial and 1 quasi-randomized controlled trial without placebo control.) Among 622 participants, 648 fractures were assessed.

Eleven trials tested LIPUS and one trial tested ECSW. Three of the 4 studies reporting on functional outcome provided limited data. One study of complete fractures found little evidence of a difference between the two groups in the time to return to work (mean difference (MD) 1.95 days favoring control, 95% CI -2.18 to 6.08). Pooled data from two studies found LIPUS did not significantly affect the time to return to training or duty in soldiers or midshipmen with stress fractures (MD -8.55 days, 95% CI -22.71 to 5.61). Results pooled from 8 studies, comprising 446 fractures, showed no statistically significant reduction in time to union of complete fractures treated with LIPUS (SMD -0.47, 95% CI -1.14 to 0.20). Pooled results from 5 of the 8 trials (333 fractures) reporting proportion of delayed union or non-union showed no significant difference between LIPUS and control (10/168 versus 13/165; RR 0.75; 95% CI 0.24 to 2.28). Adverse effects directly associated with LIPUS and associated devices were rare and not serious. One quasi-randomized study found no significant difference in non-union between internal fixation supplemented with ECSW and internal fixation alone at 12 month follow-up (3/27 versus 6/30; RR 0.56, 95% CI 0.15 to 2.01). Compared to patients receiving internal fixation alone, ECSW patients experienced significantly improved visual analogue scores for pain at 3 months follow-up (MD -0.80, 95% CI -1.23 to -0.37). None of the included studies found a difference in healing between operatively- and conservatively-managed groups receiving US. It is also unclear if/how many patients in the operative care group had previously received conservative care before surgery.

Study limitations included significant heterogeneity across studies, poor reporting of methods, and selection bias and attrition both quasi-randomized studies. Authors concluded that evidence was insufficient to support the routine use of US for the treatment of acute fractures, and called for additional trials with long-term follow-up that record functional outcomes.

Randomized Controlled Trials

In 2016, Busse and colleagues conducted an RCT evaluating the efficacy of low intensity pulsed ultrasound (LIPUS) in treatment of tibial fractures.[24] In total, 501 patients across 43 trauma centers were allocated to self-administer daily LIPUS (n=250) or use a sham device (n=251) for one year. The primary outcome of interest was time to radiographic healing within one year; the secondary outcome was rate of non-union. Other outcomes included short form 36 (SF-36) physical component summary (PCS) scores, return to work, return to household activities, return to ≥80% of function, time to full weight bearing, scores on the health utilities index, and adverse events related to the device.

Investigators reported no impact on SF-36 PCS scores between patients receiving active and sham LIPUS (mean difference 0.55, 95% confidence interval -0.75 to 1.84; p=0.41) or for the interaction between time and treatment (p= 0.30); minimal important difference is 3-5 points or in other functional measure. Patients in the two groups also experienced no difference in safety outcomes or in time to radiographic healing (hazard ration 1.07, 95% CI 0.86 to 1.34; p = 0.55). Strengths of the study include its large sample size, randomized design and blinding of patients, clinicians, data collectors, outcome assessors and data analysts. The study's primary limitation is the less than 100% follow-up for primary outcomes with a larger attrition rate for several secondary outcomes. Nonetheless, follow-up was sufficient (≥80%) to not have biased results. Additionally, although the study was initiated by investigators, the device

manufacturer provided partial funding and input. Investigators concluded that post-operative use of LIPUS after tibial fracture fixation improved neither radiographic healing nor functional recovery.

Jones' Fractures

No systematic reviews were identified that evaluated ultrasound bone growth stimulation (USBGS) for the treatment of zone two fifth metatarsal fractures (i.e., Jones' fractures). A single randomized controlled trial of 20 patients was identified (Strauss, 1999), which evaluated the treatment of Jones' fractures of the foot with adjunctive low-pulsed ultrasound stimulation.[25] Although adjunctive treatment with the USBGS (n=10) resulted in shortened healing time, the small sample size and historical nature of this non-U.S. based study does not permit meaningful conclusions. While further studies of good methodological quality are required to further validate medical necessity of USBGS for Jones' fractures, low-level evidence supports the use of this procedure.

Nonunion of a Surgical Arthrodesis

Two systematic reviews evaluated the safety and efficacy of LIPUS for the treatment of surgical nonunions,[26,27] both concluding that LIPUS lacked clinical benefit. While Mundi et al. characterized results from studies as ranging from "conflicting" to "strongly discouraging,"[27] Poolman et al issued a "strong recommendation" against LIPUS, noting that new trials were unlikely to alter the evidence.[26]

CLINICAL PRACTICE GUIDELINES

Electrical Bone Growth Stimulation

American Association of Neurological Surgeons/Congress of Neurological Surgeons (AANS/CNS)

The 2005 (updated 2014) AANS/CNS evidence-based clinical practice guideline for the performance of fusion procedures for degenerative disease of the lumbar spine: bone growth stimulators and lumbar fusion, stated, "(d)irect current stimulation or capacitive coupled stimulation are recommended as an adjunct to spinal fusion to increase fusion rates in patients who are at high risk for arthrodesis failure after lumbar posterolateral fusion."[28,29]

North American Spine Society

In 2015, the North American Spine Society recommended coverage for the adjunctive cervical use of electrical stimulation for bone healing.[30] This recommendation was made on the basis of 2 studies (1 RCT and 1 retrospective case series) with significant limitations. The RCT reported no difference in fusion rates between stimulation and control patients at 12 months' post-operation, while the validity of the case series' positive findings (i.e. 94% fusion rate) is limited by its small sample size (n=16) and retrospective design.

Ultrasound Bone Growth Stimulation

National Institute for Health and Care Excellence (NICE)

The 2019 NICE evidence-based clinical practice guideline on the EXOGEN ultrasound bone healing system for long bone fractures with non-union or delayed healing gave the following recommendations:

1. The case for adopting the EXOGEN ultrasound bone healing system to treat long bone fractures with non-union (failure to heal after 9 months) is supported by the clinical evidence, which shows high rates of fracture healing.
2. The EXOGEN ultrasound bone healing system to treat long bone fractures with non-union is associated with an estimated cost saving of £2,407 per patient compared with current management, through avoiding surgery.
3. There is some radiological evidence of improved healing when the EXOGEN ultrasound bone healing system is used for long bone fractures with delayed healing (no radiological evidence of healing after approximately 3 months). There are substantial uncertainties about the rate at which bone healing progresses without adjunctive treatment between 3 and 9 months after fracture, and about whether or not surgery would be necessary. These uncertainties result in a range of cost consequences, some cost-saving and others that are more costly than current management.[31]

EVIDENCE SUMMARY

Invasive Electrical Bone Growth Stimulation

There is sufficient evidence to support the use of invasive electrical bone growth stimulation (EBGS) as an adjunct to lumbar spinal fusion in patients who present with risk factors for failed fusion. Despite the lack of recent, reliable evidence the use of invasive EBGS has progressed into a standard of care adjunct procedure to lumbar spinal fusion for high risk patients. Furthermore, an evidence-based American Association of Neurological Surgeons/Congress of Neurological Surgeons clinic practice guidelines recommends the use of invasive EBGS in patients at a high risk for fusion failure.

There is insufficient peer-reviewed published evidence to establish the clinical utility and safety of invasive EBGS for indications outside of lumbar spinal fusion, including, but not limited to, for cervical spinal fusion and fracture nonunion. Further research of good methodological quality is required to support the use of invasive EBGS for other indications.

Noninvasive Electrical Bone Growth Stimulation

There is sufficient evidence to support the use of noninvasive electrical bone growth stimulation (EBGS) as an adjunct to lumbar spinal fusion in patients who present with risk factors for failed fusion. The evidence also establishes the effectiveness of noninvasive EBGS for the treatment of failed lumbar or cervical spinal fusion. There is sufficient evidence to establish the efficacy of noninvasive EBGS for fracture healing in patients with fracture nonunion or congenital pseudoarthroses. Furthermore, fracture nonunion and congenital pseudoarthroses patients have limited treatment options; therefore, noninvasive EBGS may be their only opportunity for improved bone healing and pain relief. No evidence-

based clinical practice guidelines were found that specifically address noninvasive EBGS as an adjunct to spinal fusion or for fracture healing.

Ultrasound Bone Growth Stimulation

There is sufficient evidence to support the safety and efficacy of ultrasound (US) bone growth stimulation (USBGS) for the treatment of nonunion fractures. Additionally, the evidence supports the hypothesis that US treatment is promoting solid fusion rather than more rapid but less substantial bone healing. Furthermore, a NICE evidence-based clinical practice guideline supports the use of US bone growth stimulation for nonunion fractures.

There is insufficient evidence to support USBGS for all other indications, including, but not limited to, delayed union fractures and fresh fractures. Additional studies of good methodological quality would be required to support the clinical utility, safety, and medical necessity of USBGS for these indications.

BILLING GUIDELINES AND CODING

E0747, E0748 and E0760 are Class III Devices which must be submitted with a KF modifier.

If codes 20974, 20975, E0748, and/or E0749 are billed in conjunction with cervical spinal fusion, they will be denied as not medically necessary and not covered.

If HCPCS code A4559 for ultrasound coupling gel or paste is billed in conjunction with ultrasound bone growth stimulation (CPT code 20979 and/or HCPCS code E0760), it should be considered medically necessary and covered.

CODES*	
A4559	Coupling gel or paste, for use with ultrasound device, per oz
Spinal Electrical Bone Growth Stimulator	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
20975	Electrical stimulation to aid bone healing; invasive (operative)
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical, surgically implanted
Non-Spinal Electrical Bone Growth Stimulator	
20974	Electrical stimulation to aid bone healing; noninvasive (nonoperative)
E0747	Osteogenesis stimulator, electrical, non-invasive, other than spinal applications
Ultrasound Bone Growth Stimulator	
20979	Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)
E0760	Osteogenesis stimulator, low intensity ultrasound, non-invasive

***Coding Notes:**

- The above code list is provided as a courtesy and may not be all-inclusive. Inclusion or omission of a code from this policy neither implies nor guarantees reimbursement or coverage. Some codes may not require routine review for

medical necessity, but they are subject to provider contracts, as well as member benefits, eligibility and potential utilization audit.

- All unlisted codes are reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is submitted for non-covered services addressed in this policy then it will be **denied as not covered**. If an unlisted code is submitted for potentially covered services addressed in this policy, to avoid post-service denial, **prior authorization is recommended**.
- **See the non-covered and prior authorization lists on the Company Medical Policy, Reimbursement Policy, Pharmacy Policy and Provider Information website for additional information.**
- HCPCS/CPT code(s) may be subject to National Correct Coding Initiative (NCCI) procedure-to-procedure (PTP) bundling edits and daily maximum edits known as "medically unlikely edits" (MUEs) published by the Centers for Medicare and Medicaid Services (CMS). This policy does not take precedence over NCCI edits or MUEs. Please refer to the CMS website for coding guidelines and applicable code combinations.

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POLICY REVISION HISTORY

DATE	REVISION SUMMARY
2/2023	Converted to new policy template.