

Electrical Stimulation for Bone Healing



DEFINING APPROPRIATE
COVERAGE POSITIONS

NASS Coverage Policy Recommendations

NASS Coverage Committee

North American Spine Society

Coverage Policy Recommendations

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Introduction

North American Spine Society (NASS) coverage policy recommendations are intended to assist payers and members by proactively defining appropriate coverage positions. Historically, NASS has provided comment on payer coverage policy upon request. However, in considering coverage policies received by the organization, NASS believes proactively examining medical evidence and recommending credible and reasonable positions may be to the benefit of both payers and members in helping achieve consensus on coverage before it becomes a matter of controversy. This coverage recommendation reflects the best available data as of 8/1/2014; information and data available after 8/1/2014 is thus not reflected in this recommendation and may warrant deviations from this recommendation, if appropriate.

Methodology

The coverage policies put forth by NASS use an evidence-based approach to spinal care when possible. In the absence of strict evidence-based criteria, policies reflect the multidisciplinary and non-conflicted experience and expertise of the authors in order to reflect reasonable standard practice indications in the United States.

NASS Coverage Policy Methodology

Scope and Clinical Indications

In 1841, Hartshorne reported on a patient with tibial nonunion who was treated with “shocks of electric fluid passed daily through the space between the ends of the bones” for six weeks.¹ Since that time, technology, devices and applications have evolved but remarkably remains based on the same base concept. The basic science behind the electrophysiology began in the early 1950s when endogenous electric fields were demonstrated when bone was deformed.²⁻⁴ Since that time, developments have been based on affecting these endogenous electric fields using an electrical stimulation device to enhance bone healing.⁵ Dwyer⁶ in 1974 described the first use of implanted direct current stimulation (DCS) for human spinal fusion.

Basic science research stimulated interest in using electrical stimulation to promote bone healing and spinal fusion. Brighton demonstrated how an influx of Calcium ions through voltage gated channels in bone cells resulted in increases to cytosolic Calcium ions, prostaglandin E2 and Calmodulin which have been found to be important in bone production.⁷ Aaron et al⁸ found that electrical stimulation and electromagnetic fields regulate the expression of genes in connective tissue cells for structural extracellular matrix proteins, resulting in increased cartilage and bone production. Finally, Wang et al⁹ demonstrated an upregulation of BMP 2, 4, 5, 6 and 7 with capacitive coupled electrical stimulation. These proteins are known to be critical in stimulating bone formation individually, and it may turn out that a combination of several BMPs working together may be even more beneficial.

Bone growth stimulators use a variety of mechanisms to achieve osteogenesis, including inductive, direct current, capacitive, magnetic and ultrasonic waves.¹⁰ Devices can be worn externally, but an implantable device for spinal fusion is available. Approximately 40% of the bone growth stimulators are used as adjuncts to spinal procedures to improve the success of spinal fusions, and the remaining 60% of the procedures are for the treatment of nonunion in long bone fractures.

A key difference in the evaluation of the bone growth stimulators is patient compliance. The size, weight and most importantly, the length of time the device must be worn affects the outcome, since a patient is more likely to comply with a convenient device than an inconvenient one. The amount of time a device must be worn or applied depends on its mode of action: Inductive devices must be worn 3-10 hours each day, while the more advanced technology, such as the magnetic stimulator, requires 30 minutes each day. The ultrasonic device requires 20 minutes each day.¹¹ Since the appropriate use of the technology requires patients to be compliant during their treatment, most of the newer devices contain software or recording mechanisms that report which days the patient used the device and for how long.

Electrical stimulation devices for the promotion of lumbar fusion consist of three types. Direct current stimulation (DCS) devices involve electrodes implanted within or very close to the location of the desired fusion. Capacitance coupling stimulation (CCS) devices involve two electrodes placed on the skin over the fusion site and connected to an external battery-powered device. With these, the patient is encouraged to use the stimulator as much as possible, up to 24 hours per day. Pulsed electromagnetic field stimulation (PEMFS) devices

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require coils (usually embedded in a brace) that produce a time-varying magnetic field around the area of the desired fusion; patients are generally instructed to wear the device for 3-8 hours per day.

According to the National Coverage Determination (NCD) for Osteogenic Stimulators, these devices have been approved: “Effective July 1, 1996, as an adjunct to spinal fusion surgery for patients at high-risk of pseudarthrosis due to previously failed spinal fusion at the same site or for those undergoing multiple level fusion. A multiple level fusion involves 3 or more vertebrae (eg, L3-L5, L4-S1, etc.).”¹²

When evaluating spine fusion, there is a challenge to correlate radiographic successful fusion with clinical outcomes. Studies vary in their reporting of this issue. Clearly, there are patients that do not achieve successful bone fusion by radiographic criteria yet obtain good outcomes. Until this issue is resolved, the economic efficacy of electrical stimulation to augment spinal fusion cannot be truly determined. However, an evaluation by the National Blue Cross Blue Shield Association’s Medical Advisory Panel of DC treatment for spinal fusions in 1992 similarly concluded that DC as an adjunct to spinal surgery improves the outcomes of patients at high-risk for pseudarthrosis.¹³ Therefore, this coverage recommendation is presented based on the assumption that successful bone fusion is required for a “successful” spinal fusion.

The general utilization of electrical stimulation devices presently is for patients at high-risk for pseudarthrosis. The premise to justify this approach is that high-risk patients that develop clinically symptomatic pseudarthrosis often require revision surgery.¹⁴ The utilization of electrical stimulation as a salvage for lumbar spinal pseudarthrosis is also limited to case studies, though a retrospective review by Simmons et al¹⁵ is promising. The indication for considering noninvasive electrical stimulation as a salvage for lumbar spinal pseudarthrosis is radiographic failure of fusion after 9 months with serial radiographs over the preceding three months failing to demonstrate evidence for progression or maturation of fusion. The FDA has approved devices for lumbar pseudarthrosis with this indication.

There are two further alternative technologies that have been applied to bone fusion, but current evidence is insufficient to support a coverage recommendation for spinal use. Low-intensity pulsed ultrasound (LIPUS) is a unique, noninvasive and low-risk treatment option for nonunion of long bone fractures though has not been studied for use in spinal fusion. Combined magnetic field (CMF) combines a static DC electric field and a sinusoidal waveform produced by external coils worn for 30 minutes daily. Cell signaling is affected through intracellular stores of calcium increasing calmodulin levels and results in bone cell proliferation. CMF became popular in the 1990s. There is a single study from Linovitz et al¹⁶ supporting increased fusion rates with non-instrumented posterolateral lumbar fusion.

Coverage Recommendations

Electrical stimulation for spinal fusion healing is indicated in the following clinical scenario(s) with qualifying criteria, when appropriate:

1. For augmentation of spinal fusion in any and all regions of the spine including occipital-cervical, cervical, cervicothoracic, thoracic, thoracolumbar, lumbar and lumbosacral spinal regions in patients at high-risk for the development of pseudarthrosis (ie, nonunion) who exhibit one or more of the following:
 - a) Are undergoing spinal fusion of two or more motion segments (3 vertebrae)
 - b) Are undergoing a revision spinal fusion (eg, repeat surgery for a previously unhealed fusion attempt)
 - c) Are smokers who cannot stop smoking in preparation for fusion due to the nature of the underlying condition (eg, acute traumatic fracture)
 - d) Exhibit one or more of the following comorbidities when undergoing primary lumbar fusion:
 - i. Diabetes
 - ii. Inflammatory arthritis (eg, rheumatoid arthritis) that has required long-term corticosteroid therapy
 - iii. Immunocompromised (eg, undergoing chemotherapy and radiation therapy to the spine, hypogammaglobulinemia, granulocytopenia, acquired immune deficiency syndrome, chronic granulomatous disease)
 - iv. Systemic vascular disease
 - v. Osteopenia or osteoporosis
2. In the lumbar spine, the following forms of electrical stimulation are indicated in high-risk patients with the specific techniques outlined. In all other regions of the spine, coverage for the same indications is recommended although there is less supporting evidence.
 - a) DCS and CCS for posterolateral fusion using autograft and extender
 - b) PEMFS for lumbar interbody fusion

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Electrical stimulation of spinal fusion is NOT indicated in the following clinical scenarios at this time:

1. Primary (index or first-attempt) spinal fusions without additional risk factors listed above
2. Spinal fusion of one motion segment or (2 vertebrae) levels without additional risk factors listed above
3. Presence of malignancy
4. Current evidence is insufficient to recommend for or against the use of electrical stimulation:
 - a) As an adjunct for primary bone healing of a spinal fracture
 - b) As a nonsurgical treatment of an established pseudarthrosis

There are a number of clinical situations in which the safety of an electrical stimulation device, independent of the above scenarios and indications, should be considered specifically:

1. Pregnancy: The safety of these devices for use on patients who are pregnant or nursing has not been established.
2. Infection: Electrical stimulation may have a theoretical advantage by disrupting the bacterial biofilm though an animal study failed to show an improvement but did not show an increase in infection. An older clinical study that does not meet evidence based standards states that electrical stimulation is safe for chronic spinal infections. Therefore, infection does not appear to be a contraindication to the use of electrical stimulation.
3. Patient with Cardiac Pacemakers or Defibrillators: Consultation with a cardiologist is indicated prior to the use of electrical stimulation for any patient who has a cardiac pacemaker or defibrillator.
4. Children (skeletal immaturity): The safety of electrical stimulation in skeletally immature patients has not been verified although there is case report literature on the use of the technology in adolescents with spondylolysis, and no adverse events have been documented.
5. Patients who will require MRI studies:
 - a) Externally applied electrical stimulation devices should be removed prior to an MRI.
 - b) Implanted electrical stimulation devices for spinal fusion are considered safe and indicated for patients who will be undergoing MRI procedures under the following conditions:
 - i. MRI static magnetic field of 1.5 Tesla or less
 - ii. Maximum spatial gradient 250 gauss/cm for the SpF PLUS-Mini model and maximum spatial gradient 450 gauss/cm for the SpF-XL IIb model
 - iii. Gradient magnetic fields of 20 Tesla/second or less
 - iv. Maximum whole body averaged Specific Absorption Rate (SAR) of 1.1 W/kg for 25 minutes of imaging

Rationale

Overall, all of these studies have methodology flaws especially in outcome evaluations. However, there does appear to be adequate evidence-based medicine documentation to support the positive effect of electrical stimulation on bone fusion, mostly documented for lumbar fusion and primarily posterior lumbar fusion (PLF).

There does appear to be favorable fusion rates with DCS when used with PLF. Andersen et al¹⁷ failed to show benefit with DCS on PLF when allograft was used. Allograft used as an extender to autograft did not have an adverse effect on DCS effect on PLF.

There does appear to be favorable improved fusion rates with CCS for PLF with positive results in Resnick, Kaiser and Goodwin, and no negative results documented.¹⁸⁻²⁰

There is suggestive evidence for PEMFS for PLF with positive results in Bose, Di Silvestre and Marks.²¹⁻²³ Jenis et al²⁴ failed to show benefit of PEMFS for PLF.

Four papers addressed the usage of electrical stimulation for lumbar interbody fusion. Dwyer and Meril suggest improved fusion rates for DCS on lumbar interbody fusion.²⁵⁻²⁶ Resnick, Kaiser, Marks and Mooney support a favorable improved fusion rates with PEMFS on lumbar interbody fusion.^{18-19,23,27} There were no papers evaluating the effect of CCS on lumbar interbody fusion.

Two papers addressed adjunctive usage of electrical stimulation for cervical fusion. Foley et al²⁸ failed to show significant difference with PEMFS on anterior cervical discectomy and fusion (ACDF) using allograft. Welch et al²⁹ suggested positive effect of DCS on posterior cervical fusion.

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The utilization of electrical stimulation as primary treatment of spondylolysis is limited to case studies, primarily in young patients, though it does suggest successful radiographic fusion.³⁰


The utilization of non-invasive electrical stimulation for “delayed union” of lumbar fusion with or without risk factors might be considered if there is failure to demonstrate progressive maturation of bone fusion between months 3 through 6 to prevent “true” pseudarthrosis. There is no literature addressing this interesting issue at this time.

Most studies focused on randomization of patients to compare the effect of electrical stimulation to those without electrical stimulation on lumbar fusion though analysis would address accepted high-risk factors when available. Meril et al²⁶ defines high-risk factors as smokers, L4-5 level and two level fusions for which DCS was successful. Goodwin et al²⁰ defined high-risk factors as smokers and two level fusions. He concluded the CCS did not overcome these risk factors, but DCS in instrumented PLF did overcome these risk factors. In a review article by Morone and Feuer³¹, high-risk criteria was listed as prior spinal surgery, especially fusion, multilevel fusions, poor nutritional status, nicotine usage (smokers), steroids and NSAIDs, grade 2+ spondylolisthesis, low bone mineral density (osteopenia and osteoporosis), obesity and diabetes.


There are studies that were designed to directly study the efficacy of electrical stimulation in patients with predefined high-risk factors. Kucharzyk et al³² studied DCS for instrumented PLF in high-risk patients defined as smokers, multiple prior lumbar surgeries and certain medical conditions (diabetes, hypertension, thyroid and parathyroid diseases and obesity) and demonstrated that DCS for instrumented PLF did overcome these high-risk factors. Rogozinski et al³³ studied DCS for instrumented PLF in patients with high-risk factors defined as smokers, previous back surgery and multilevel fusions. They concluded that DCS did overcome these high-risk factors for instrumented PLF. Kane et al³⁴ demonstrated that DCS for PLF did overcome high-risk factors defined as pseudarthrosis, grade 2+ spondylolisthesis, multilevel fusions and obesity. Tejano et al³⁵ demonstrated that DCS for uninstrumented PLF did overcome the risk factor of multilevel fusions. In a small retrospective study, Welch et al²⁹ studies DCS for posterior cervical fusion (PCF) in high-risk patients defined as advanced age, rheumatoid arthritis, pseudarthrosis, infection and immunosuppressive drugs. This study suggested that DCS did overcome these risk factors.

Again, these studies have methodological, follow up and outcome flaws with no consistent definition of high-risk factors. The Coverage Recommendations are based on accepted high-risk factors from clinical experience combined with the available best evidence in the peer review literature.



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Kennedy, D.J.: Speaking and/or Teaching Arrangements: Spine Intervention Society (Travel expenses); Trips/Travel: AAPM&R (Travel

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expenses), Spine Intervention Society (A); Board of Directors: AAPM&R (Board of Directors – Member At Large), Spine intervention Society (Treasurer), Association of Academic Physiatrists (Board of Directors - Chair of Membership Committee).

Kreiner, Scott: Speaking and/or Teaching Arrangements: North American Spine Society (Travel expenses), SIS (Travel expenses).

Lapinsky, Anthony S.: Nothing to disclose.

Lebl, Darren R.: Speaking and/or Teaching Arrangements: Medtronic (B); Scientific Advisory Board: K2M MIS Advisory Team (B).

Matz, Paul G.: Speaking and/or teaching arrangements: AO Spine North America (B).

Mayer, E. Kano A.: Consulting: Inspire Sleep (B); Speaking and/or Teaching Arrangements: North American Spine Society (B); Trips/Travel: Spine Injection Society (A), North American Spine Society (B).

O'Brien Jr., David R.: Board of Directors: North American Spine Society (Health Policy Council Director).

Patel, Alpesh A.: Royalties: Amedica (B); Stock Ownership: Amedica (<1%), Cytonics (<1%), Nocimed (<1%), Vital5 (<1%); Consulting: Amedica (None), Stryker (None), Biomet (C), DePuy Synthes Spine (B); Board of Directors: Cervical Spine Research Society (None); Fellowship Support: OREF (A), Omega (B); Other: Amedica (Private investment, <1%).

Reiter, Mitchell F.: Private Investments: CreOsso (4%).

Reitman, Charles A.: Trips/Travel: North American Spine Society (Travel expenses); Board of Directors: North American Spine Society (Research Council Director); Scientific Advisory Board: Clinical Orthopedics and Related Research (B, Deputy Editor, Paid directly to institution/employer).

Sanford, Timothy: Nothing to disclose.

Seldomridge, Alex: Nothing to disclose.

Sharan, Alok D.: Consulting: Paradigm Spine (B); Other: Jaypee Brothers (A).

Smuck, Matthew: Stock Ownership: NuSpine (1%), BlueJay Mobile-Health (1%); Private Investments: Vivametrika/Sikoya (20%, Founding partner); Trips/Travel: SIS (B), North American Spine Society (B); Board of Directors: Vivametrika/Sikoya (None), SIS (None), North American Spine Society (None); Scientific Advisory Board: NuSpine (Stock options), Lumo Body Tech (Stock options), BlueJay Mobile-Health (Stock options); Other Office: The Spine Journal (Deputy Editor), SIS (Board of Directors), North American Spine Society (Board of Directors); Other: Expert witness - State Farm (F), Expert witness - Kaiser Permanente (C); Relationships Outside the One-Year Requirement: Cytonics, Inc. (Research Support: Staff and/or Materials, F, dissolved in 2011).

Summers, Jeffrey T.: Stock Ownership: NEVRO (1%); Board of Directors: First Choice Insurance (Representative for Pain Management), SIS (Board Member and Past President, Travel expenses).

Tontz, William L.: Device or Biologic Distributorship (Physician-Owned Distributorship): Aliphatic (A, Paid directly to institution/employer); Stock Ownership: Phygen (<1%, Paid directly to institution/employer); Consulting: Medtronic (B, Paid directly to institution/employer); Speaking and/or Teaching Arrangements: SpineArt (A); Trips/Travel: Stryker (B); Scientific Advisory Board: Medtronic (Consulting Disclosed Above).

Tromanhauser, Scott G.: Stock Ownership: Soteira, Inc. (1%); Consulting: Boston Biomedical Associates (B); Board of Directors: New England Baptist Hospital (Ex Officio member of the Board of Trustees); Other Office: Controlled Risk Insurance Company (Board-level committee member, provided with travel and lodging expenses for annual meetings only).

Truumees, Eric: Royalties: Stryker Spine (C); Stock Ownership: Doctor's Research Group (<1%); Board of Directors: North American Spine Society (Administration and Development Council Director); Other Office: AAOS Communications Cabinet (Incoming Editor-in-Chief of AAOS Now, Travel expenses, Monthly stipend); Research Support - Investigator Salary: Relievan (B, Paid directly to institution/employer); Research Support - Staff and/or Materials: Globus (B, Paid directly to institution/employer); Relationships Outside the One-Year Requirement: IP Evolutions (Private Investment, dissolved 2012), Stryker Biotech (Research Support, Paid directly to institution/employer, dissolved 2004).

Comments

Comments regarding the coverage recommendations may be submitted to coverage@spine.org and will be considered in development of future revisions of the work.

Disclosure Key

Direct or indirect remuneration: royalties, stock ownership, private investments, consulting, speaking and/or teaching arrangements, trips/travel. **Position held in a company:** board of directors, scientific advisory board, other office. **Support from sponsors:** endowments, research-investigator salary, research-staff and/or materials, grants, fellowship support. **Other**

Degree of support:

Level A.	\$100 to \$1000	Level F.	\$100,001 to \$500,000
Level B.	\$1,001 to \$10,000	Level G.	\$500,001 to \$1M
Level C.	\$10,001 to \$25,000	Level H.	\$1,000,001 to \$2.5M
Level D.	\$25,001 to \$50,000	Level I.	greater than \$2.5M
Level E.	\$50,001 to \$100,000		

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NASS Coverage Recommendations Methodology

Topic Selection:

Coverage Recommendations topic lists are developed and approved by the Coverage Committee. Topics include both therapeutic and diagnostic procedures and treatments as well as nonoperative, interventional, and surgical procedures and treatments. The breadth of the topics attempts to represent all facets of spinal care. Topics are selected based on frequency of use in spine care and will attempt to represent the full breadth of procedures, diagnostics, and interventions.

Author Assignment:

The Coverage Committee members rank their preferences (1, 2, or 3) for topic assignment. The Chair matches topics to the members' preferences as much as possible. Active consideration is given to avoiding conflicts of interest, whether financial or otherwise, between members and the topics assigned. All authors disclose any conflicts of interest in accordance with the [NASS disclosure policy](#).

Background Data Review:

For each topic, authors coordinate a literature search with the help of a research librarian/NASS staff member.

A literature search using PubMed, EMBASE, Web of Science and Cochrane is performed using search terms identified by the author specific to the topic assigned. Searches are limited to systematic reviews, meta-analyses, clinical guidelines, and most importantly, randomized controlled trials. The search produces a list of abstracts to be sent to the author for review and selection of appropriate articles for full review. Selected articles are then be sent to the Coverage Committee Chair for the approval to reduce any potential bias. The National Guidelines Clearinghouse is also be searched by NASS staff for appropriate clinical guidelines. Note that only full text, peer-reviewed articles published in English are eligible for review. Abstracts and non-published reports are not eligible for review.

In addition, NASS staff identify and retrieve any previously issued coverage policy on the topic, either by a private or public insurance provider.

Data Analysis:

The medical literature is analyzed with preference given to the highest quality literature available. Funding and other potential sources of bias are taken into consideration, as is consistency of the literature reviewed. In the absence of high-level data, coverage recommendations reflect the multi-disciplinary experience and expertise of the committee members in order to present reasonable standard practice indications in the United States.

Coverage Recommendations Formulation:

When trials, guidelines, or systematic reviews are available, the coverage recommendations should reflect the published data as much as possible. However, given the complexities of clinical care and the limitations of the medical literature in many circumstances, additional consideration is given to specific clinical scenarios and the currently available treatment options for those scenarios, including the potential risks and benefits of the alternative treatment options, prior to establishing a coverage decision. In summary, final determinations are made upon an evidence-based review of the existing data, an understanding of clinical care, and the NASS mission.

Individual coverage recommendations follow a standard format document approval: Once formulated, the coverage recommendations are reviewed and revised by the Coverage Committee Chair incorporating any new data if available since the document is developed and with modifications for format. The document is then sent to the senior reviewers of the Coverage Committee and subject-matter experts from the NASS' Payor Policy Review Committee (PPRC) for review and comment. After review at this level, final modifications are made and author is advised. The proposed coverage document is sent to the NASS Executive Committee of the board directors for review and final approval before publication. The proposed coverage document is published on NASS' website with a 30-day public comment period. At the end of the public comment period, comments are reviewed and considered by the NASS Coverage Committee. Where appropriate, the Committee makes edits and then publish the final document on NASS website.

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NASS Resources

Clinical Guidelines

[Diagnosis and Treatment of Adult Isthmic Spondylolisthesis](#) 

[Diagnosis and Treatment of Degenerative Spondylolisthesis \(Revised 2014\)](#) 

[Diagnosis and Treatment of Lumbar Disc Herniation with Radiculopathy](#) 

[Antibiotic Prophylaxis in Spine Surgery \(Revised 2013\)](#) 

[Diagnosis and Treatment of Degenerative Lumbar Spinal Stenosis \(Revised 2011\)](#) 

[Diagnosis and Treatment of Cervical Radiculopathy from Degenerative Disorders](#) 

[Antithrombotic Therapies in Spine Surgery](#) 

Appropriate Use Criteria

[Cervical Fusion](#) 

Coding FAQs (NASS Member Resource Only)

Patient Education Brochures (Complete Catalog)

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NASS Coverage Policy Recommendations

**Electrical Stimulation
for Bone Healing**

**North American Spine Society
7075 Veterans Boulevard
Burr Ridge, IL 60527
(630) 230-3600**