

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy Electrical Stimulation of the Spine as an Adjunct to Spinal Fusion Procedures

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Policy Number: 498

BCBSA Reference Number: 7.01.85 NCD/LCD: NA

Related Policies

- Ultrasound Accelerated Fracture Healing Device, #497
- Electrical Bone Growth Stimulation of the Appendicular Skeleton, #499
- Bone Morphogenetic Protein, #097

Policy

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

Either invasive or noninvasive methods of electrical bone growth stimulation may be <u>MEDICALLY</u> <u>NECESSARY</u> as an *adjunct* to lumbar spinal fusion surgery in patients at high risk for fusion failure, defined as any one of the following criteria:

- One or more previous failed spinal fusion(s),
- Grade III or worse spondylolisthesis,
- Fusion to be performed at more than one level,
- Current tobacco use,
- Diabetes,
- Renal disease,
- Alcoholism, and
- Steroid use.

Noninvasive electrical bone stimulation may be <u>MEDICALLY NECESSARY</u> as a treatment of patients with failed lumbar spinal fusion. Failed spinal fusion is defined as a spinal fusion that has not healed at a minimum of 6 months after the original surgery, as evidenced by serial x-rays over a course of 3 months.

Semi-invasive electrical stimulation is **INVESTIGATIONAL** as an adjunct to lumbar fusion surgery and for failed lumbar fusion.

Non-invasive electrical bone growth stimulation for treatments that do not meet the criteria noted above are **INVESTIGATIONAL**.

Invasive, semi-invasive, and noninvasive electrical stimulation are **<u>INVESTIGATIONAL</u>** as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> <u>required</u> if the procedure is performed <u>outpatient</u>.

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is not required .
Commercial PPO and Indemnity	Prior authorization is not required .
Medicare HMO Blue sm	Prior authorization is not required .
Medicare PPO Blue SM	Prior authorization is not required .

CPT Codes / HCPCS Codes / ICD Codes

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

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

CPT Codes

CPT codes:	Code Description
20974	Electrical stimulation to aid bone healing; noninvasive (non-operative)
20975	Electrical stimulation to aid bone healing; invasive (operative)

HCPCS Codes

HCPCS	
codes:	Code Description
E0748	Osteogenesis stimulator, electrical, non-invasive, spinal applications
E0749	Osteogenesis stimulator, electrical (surgically implanted

Description

Electrical Bone Growth Stimulators

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the probability of obtaining a solid spinal fusion. Noninvasive devices have also been investigated to treat a failed fusion. Electrical and electromagnetic fields can be generated and applied to bones through surgical, noninvasive, and semi-invasive methods.

Invasive Stimulators

Invasive devices require surgical implantation of a current generator in an intramuscular or subcutaneous space, with an accompanying electrode implanted within the fragments of bone graft at the fusion site. The implantable device typically remains functional for six to nine months after implantation, and although the current generator is removed in a second surgical procedure when stimulation is completed, the electrode may or may not be removed. Implantable electrodes provide constant stimulation at the nonunion or fracture site but carry increased risks associated with implantable leads.

Noninvasive Stimulators

Noninvasive electrical bone growth stimulators generate a weak electrical current within the target site using either pulsed electromagnetic fields, capacitive coupling, or combined magnetic fields. In capacitive coupling, small skin pads/electrodes are placed on either side of the fusion site and are worn for 24 hours a day until healing occurs, or for up to 9 months. In contrast, pulsed electromagnetic fields are delivered via treatment coils that are placed into a back brace or directly onto the skin and are worn for six to eight hours a day for three to six months. Combined magnetic fields deliver a time-varying magnetic field by superimposing the time-varying field onto an additional static magnetic field. This device involves 30 minutes of treatment daily for 9 months. Patient compliance may be an issue with externally worn devices.

Semi-Invasive Stimulators

Semi-invasive (semi-implantable) stimulators use percutaneous electrodes and an external power supply, obviating the need for a surgical procedure to remove the generator when treatment is finished.

Summary

Both invasive and noninvasive electrical bone growth stimulators have been investigated as an adjunct to spinal fusion surgery, with or without associated instrumentation, to enhance the probability of obtaining a solid spinal fusion. Noninvasive devices have also been investigated in patients who are at normal risk of failed fusion and to treat a failed fusion.

For individuals who are at high-risk of lumbar spinal fusion surgery failure who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes systematic reviews, a TEC Assessment, and randomized controlled trials. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Results from these trials have indicated that in patients with risk factors for failed fusion surgery, either invasive or noninvasive electrical bone stimulation increases the fusion rate. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have failed lumbar spinal fusion surgery who receive noninvasive electrical bone growth stimulation, the evidence includes a TEC Assessment and studies with patients serving as their own controls. Relevant outcomes are symptoms, change in disease status, and functional outcomes. Data have shown that noninvasive electrical stimulation improves fusion rates in this population. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who are undergoing cervical spinal fusion surgery or have failed cervical spine fusion who receive invasive or noninvasive electrical bone growth stimulation, the evidence includes a randomized controlled trial. Relevant outcomes are symptoms, change in disease status, and functional outcomes. The only controlled trial published to date had methodologic limitations, and the efficacy of electrical stimulation in the cervical spine has not been established. An open-label multicenter cohort study provided evidence to demonstrate that patients at high-risk for arthrodesis following anterior cervical discectomy and fusion procedures reported statistically significant improvements in fusion rates with pulsed electromagnetic field stimulation. However, limitations on surgical methods used by surgeons, preclude definitive assessments of treatment efficacy. The evidence is insufficient to determine the effects of the technology on health outcomes.

Date	Action
6/2020	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2019	BCBSA National medical policy review. Description, summary and references updated. Policy statements unchanged.
5/2018	New references added from BCBSA National medical policy. Background and summary clarified.
5/2017	New references added from BCBSA National medical policy.

Policy History

5/2016	New references added from BCBSA National medical policy.
12/2014	New references added from BCBSA National medical policy.
12/2013	Added LCD: L11501 to the policy.
11/2011-	Medical policy ICD 10 remediation: Formatting, editing and coding updates.
4/2012	No changes to policy statements.
6/2011	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
4/2011	BCBSA National medical policy review.
	No changes to policy statements.
7/2010	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
12/2009	BCBSA National medical policy review.
	Changes to policy statements.
7/2009	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
7/2008	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
7/2007	Reviewed - Medical Policy Group - Orthopedics, Rehabilitation Medicine and
	Rheumatology.
	No changes to policy statements.
6/2007	BCBSA National medical policy review.
	Changes to policy statements.

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: <u>Medical Policy Terms of Use</u> <u>Managed Care Guidelines</u> <u>Indemnity/PPO Guidelines</u> <u>Clinical Exception Process</u> <u>Medical Technology Assessment Guidelines</u>

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