MEDICAL POLICY

POLICY TITLE	ELECTRICAL STIMULATION OF THE SPINE AS AN ADJUNCT TO SPINAL FUSION PROCEDURES
POLICY NUMBER	MP 1.150

CLINICAL BENEFIT	☐ MINIMIZE SAFETY RISK OR CONCERN. ☐ MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS. ☐ ASSURE APPROPRIATE LEVEL OF CARE. ☐ ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS. ☒ ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET. ☐ ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE.
Effective Date:	**10/1/2024**

I. POLICY

Either invasive or noninvasive methods of electrical bone growth stimulation may be considered **medically necessary** as an *adjunct* to lumbar spinal fusion surgery in individuals at high risk for fusion failure, defined as any **one** of the following criteria:

- one or more previous failed spinal fusion(s); **or**
- grade III or worse spondylolisthesis; **or**
- fusion to be performed at more than one (1) level; **or**
- current tobacco use; **or**
- diabetes; **or**
- renal disease; **or**
- alcoholism; **or**
- steroid use; **or**
- immunocompromised status; **or**
- osteoporosis

The above methods are **not medically necessary** as an *adjunct* to cervical or thoracic spinal fusion surgery in individuals at high risk for fusion failure.

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as a treatment of individuals 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 radiographs over a course of 3 months.

For failed cervical or thoracic spinal fusion, noninvasive electrical bone growth stimulation is considered **not medically necessary.**

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Semi-invasive electrical bone growth stimulation is considered **investigational** as an adjunct to spinal fusion surgery and for failed spinal fusion. There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Invasive, semi-invasive, and noninvasive electrical bone growth stimulation is considered **investigational** for the following indication (this list is not all-inclusive):

- As an adjunct for healing of lumbar spondylolysis (pars interarticularis defect/fracture)

There is insufficient evidence to support a general conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:

MP 1.024 Electrical Bone Growth Stimulation of the Appendicular Skeleton
MP 6.021 Low Intensity Pulsed Ultrasound Fracture Healing Device (Formerly Ultrasound Accelerated Fracture Healing Device)

II. PRODUCT VARIATIONS

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This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations as discussed in Section VI. Please see additional information below.

FEP PPO - Refer to FEP Medical Policy Manual. The FEP Medical Policy manual can be found at:
https://www.fepblue.org/benefit-plans/medical-policies-and-utilization-management-guidelines/medical-policies

III. DESCRIPTION/BACKGROUND

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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 6 to 9 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.

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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 6 to 8 hours a day for 3 to 6 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.

REGULATORY STATUS
The following implantable device was approved by the U.S. Food and Drug Administration (FDA) through the premarket approval process:

- In 1986, the OsteoStim® (Electro-Biology), which may also be marketed under the trade name SPF (Biomet).

The following noninvasive bone growth stimulators have been approved by FDA through the premarket approval process:

- In 1999, the SpinalPak® bone growth stimulator system (Biolectron, a subsidiary of Electro-Biology), a capacitive coupling system, was approved for use as an adjunct to primary lumbar spinal fusion at 1 or 2 levels.
- In 1979, the EBI Bone Healing System® (Biolectron, a subsidiary of Electro-Biology), a pulsed electromagnetic field system, was approved for nonunions, failed fusions, and congenital pseudoarthroses. The device is secured with a belt around the waist.
- In 1994, the SpinaLogic Bone Growth Stimulator® (Regentek, a division of dj Orthopedics [formerly OrthoLogic]) was approved as a combined magnetic field portable device. This device is secured with a belt around the waist.
- In 1996, the Spinal-Stim Lite® (Orthofix) was approved as a spinal adjunct to the Physio-Stim®. The Spinal-Stim Lite® device was approved to increase the probability of fusion success and as a nonoperative treatment for the salvage of failed spinal fusion, where a minimum of 9 months has elapsed since the last surgery.
- In 2004, the Stim® (Orthofix), a pulsed electromagnetic field system, was approved as an adjunct to cervical fusion surgery in patients at high risk for nonfusion.

In 2020, the ActaStim-S Spine Fusion Stimulator (Theragen, Inc.), was approved as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels. This device is secured with a belt around the waist.

No semi-invasive electrical bone growth stimulator devices were identified with FDA approval or clearance.

FDA product codes: LOE (invasive bone growth stimulator), LOF (noninvasive bone growth stimulator).

IV. RATIONALE

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Summary of Evidence

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 RCTs. 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 an RCT. 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 in the study design, including use of a historical control group, lack of blinding, and no restrictions 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.

Clinical input was received in 2021 by an external reviewer who agreed with performing this procedure only on the lumbar spine as non-unions in the cervical and thoracic spine are uncommon.

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V. DEFINITIONS

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NA

VI. BENEFIT VARIATIONS

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The existence of this medical policy does not mean that this service is a covered benefit under the member's health benefit plan. Benefit determinations should be based in all cases on the applicable health benefit plan language. Medical policies do not constitute a description of benefits. A member's health benefit plan governs which services are covered, which are excluded, which are subject to benefit limits, and which require preauthorization. There are different benefit plan designs in each product administered by Capital Blue Cross. Members and providers should consult the member's health benefit plan for information or contact Capital Blue Cross for benefit information.

VII. DISCLAIMER

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Capital Blue Cross' medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. If a provider or a member has a question concerning the application of this medical policy to a specific member's plan of benefits, please contact Capital Blue Cross' Provider Services or Member Services. Capital Blue Cross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

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Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

Not medically necessary/investigational for the following services:

- Semi-invasive electrical bone growth stimulation as an adjunct to spinal fusion surgery or failed spinal fusion;
- Invasive and noninvasive electrical bone growth stimulation as an adjunct to cervical or thoracic fusion surgery or failed cervical or thoracic spine fusion; and
- Invasive, semi-invasive, and noninvasive electrical bone growth stimulation as an adjunct for healing of lumbar spondylolysis (Pars interarticularis defect/fracture):

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Procedure Codes							
E0748	E0749	20974	20975				

Covered when medically necessary; electrical bone growth stimulation (invasive or noninvasive) as an adjunct to lumbar spinal fusion surgery in individuals at high risk for fusion failure:

Procedure Codes							
E0748	E0749	20974	20975				

ICD-10-CM Diagnosis Codes	Description
M43.15	Spondylolisthesis, thoracolumbar region
M43.16	Spondylolisthesis, lumbar region
M43.17	Spondylolisthesis, lumbosacral region
M43.19	Spondylolisthesis, multiple sites in spine
M43.25	Fusion of spine, thoracolumbar region
M43.26	Fusion of spine, lumbar region
M43.27	Fusion of spine, lumbosacral region
M48.05	Spinal stenosis, thoracolumbar region
M48.061	Spinal stenosis, lumbar region without neurogenic claudication
M48.062	Spinal stenosis, lumbar region with neurogenic claudication
M48.07	Spinal stenosis, lumbosacral region
M51.05	Intervertebral disc disorders with myelopathy, thoracolumbar region
M51.06	Intervertebral disc disorders with myelopathy, lumbar region
M51.15	Intervertebral disc disorders with radiculopathy, thoracolumbar region
M51.16	Intervertebral disc disorders with radiculopathy, lumbar region
M51.17	Intervertebral disc disorders with radiculopathy, lumbosacral region
M51.25	Other intervertebral disc displacement, thoracolumbar region
M51.26	Other intervertebral disc displacement, lumbar region
M51.27	Other intervertebral disc displacement, lumbosacral region
M51.35	Other intervertebral disc degeneration, thoracolumbar region
M51.360	Other intervertebral disc degeneration, lumbar region with discogenic back pain only
M51.361	Other intervertebral disc degeneration, lumbar region with lower extremity pain only

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ICD-10-CM Diagnosis Codes	Description
M51.362	Other intervertebral disc degeneration, lumbar region with discogenic back pain and lower extremity pain
M51.369	Other intervertebral disc degeneration, lumbar region without mention of lumbar back pain or lower extremity pain
M51.370	Other intervertebral disc degeneration, lumbosacral region with discogenic back pain only
M51.371	Other intervertebral disc degeneration, lumbosacral region with lower extremity pain only
M51.372	Other intervertebral disc degeneration, lumbosacral region with discogenic back pain and lower extremity pain
M51.379	Other intervertebral disc degeneration, lumbosacral region without mention of lumbar back pain or lower extremity pain
M51.45	Schmorl's nodes, thoracolumbar region
M51.46	Schmorl's nodes, lumbar region
M51.47	Schmorl's nodes, lumbosacral region
M51.85	Other intervertebral disc disorders, thoracolumbar region
M51.86	Other intervertebral disc disorders, lumbar region
M51.87	Other intervertebral disc disorders, lumbosacral region

Covered when medically necessary; noninvasive electrical bone growth stimulation for failed lumbar spinal fusion:

Procedure Codes							
E0748	20974						

ICD-10-CM Diagnosis Codes	Description
T84.418A	Breakdown (mechanical) of other internal orthopedic devices, implants and grafts, initial encounter
T84.418D	Breakdown (mechanical) of other internal orthopedic devices, implants and grafts, subsequent encounter
T84.418S	Breakdown (mechanical) of other internal orthopedic devices, implants and grafts, sequela
T84.498A	Other mechanical complication of other internal orthopedic devices, implants and grafts, initial encounter
T84.498D	Other mechanical complication of other internal orthopedic devices, implants and grafts, subsequent encounter

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ICD-10-CM Diagnosis Codes	Description
T84.498S	Other mechanical complication of other internal orthopedic devices, implants and grafts, sequela

IX. REFERENCES

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X. POLICY HISTORY

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MP 1.150	**03/19/2020 Consensus Review.** Policy statement unchanged. References reviewed. Coding and Background updated.
	06/08/2021 Minor Review. Added immunocompromised status and osteoporosis to MN criteria. Changed cervical from INV to not medically necessary along with thoracic. Updated cross-references, FEP, Rationale, and coding section language. However, the CPT codes did not change.
	03/31/2022 Consensus Review. No changes to policy statement. FEP updated. Coding and references reviewed.
	06/21/2023 Consensus Review. No change to policy statement. Regulatory status updated. References updated. References and coding reviewed. No coding changes.
	04/24/2024 Consensus Review. No change to policy statement. References updated. Coding reviewed with no coding changes.
	8/16/2024 Administrative Update. Removed old ICD-10 codes M51.36 and M51.37. Added new ICD-10 codes M51.360, M51.361, M51.362, M51.369, M51.370, M51.371, M51.372, and M51.379. Codes effective from 10/1/24.

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