

## MEDICAL POLICY

|                  |                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
|------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| POLICY TITLE     | ELECTRICAL STIMULATION OF THE SPINE AS AN ADJUNCT TO SPINAL FUSION PROCEDURES                                                                                                                                                                                                                                                                                                                                                                                             |
| POLICY NUMBER    | MP 1.150                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| CLINICAL BENEFIT | <input type="checkbox"/> MINIMIZE SAFETY RISK OR CONCERN.<br><input type="checkbox"/> MINIMIZE HARMFUL OR INEFFECTIVE INTERVENTIONS.<br><input type="checkbox"/> ASSURE APPROPRIATE LEVEL OF CARE.<br><input type="checkbox"/> ASSURE APPROPRIATE DURATION OF SERVICE FOR INTERVENTIONS.<br><input checked="" type="checkbox"/> ASSURE THAT RECOMMENDED MEDICAL PREREQUISITES HAVE BEEN MET.<br><input type="checkbox"/> ASSURE APPROPRIATE SITE OF TREATMENT OR SERVICE. |
| Effective date:  | 8/1/2026                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

### 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.

Noninvasive electrical bone growth stimulation may be considered **medically necessary** as a treatment for individuals with failed lumbar spinal fusion surgery. 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.

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

#### Cross-References:

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

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### PRODUCT VARIATIONS

This policy is only applicable to certain programs and products administered by Capital Blue Cross and subject to benefit variations. 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>

### DESCRIPTION/BACKGROUND

#### 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 in patients who are at normal risk of failed fusion and 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. 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 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.

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### REGULATORY STATUS

Table 1 summarizes the FDA cleared or approved noninvasive and implantable electrical bone growth stimulator devices. No semi-invasive electrical bone growth stimulator devices with the FDA approval or clearance were identified.

The FDA has approved labeling changes for electrical bone growth stimulators that remove any time frame for the diagnosis. In September 2020, FDA considered the reclassification of noninvasive electrical bone growth stimulators from Class 3 to the lower-risk Class 2 category. As of March 2025, however, the devices remain Class 3.

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

**Table 1: U.S. Food and Drug Administration-Approved Electrical Bone Growth Stimulator devices**

| Device                                                       | Indication                                                                                                                                                                                                                                                                            | Manufacturer                     | Date Approved | PMA No.      |
|--------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|---------------|--------------|
| <b><i>Noninvasive Electrical Bone Growth Stimulators</i></b> |                                                                                                                                                                                                                                                                                       |                                  |               |              |
| BIO Osteogen System 204 (now EBI Bone Healing System)        | <ul style="list-style-type: none"> <li>Indicated for the treatment of a variety of conditions, including non-unions, congenital pseudarthrosis, and certain fractures.</li> <li>A pulsed electromagnetic field system. The device is secured with a belt around the waist.</li> </ul> | EBI, LLC (now Highridge Medical) | 1979          | P790002      |
| SpinalPak® Non-invasive Spine Fusion Stimulator System       | <ul style="list-style-type: none"> <li>Indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels</li> <li>A capacitive coupling system, approved for use as an adjunct to primary lumbar</li> </ul>                                  | EBI, LLC (now Highridge Medical) | 1986          | P850022/S017 |

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|                                                 |                                                                                                                                                                                                                                                                                |                  |      |              |
|-------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|------------------|------|--------------|
|                                                 | spinal fusion at 1 or 2 levels.                                                                                                                                                                                                                                                |                  |      |              |
| SpinaLogic Bone Growth Stimulator®              | <ul style="list-style-type: none"> <li>Indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels. Approved as a combined magnetic field portable device. This device is secured with a belt around the waist.</li> </ul> | DJO (now Enovis) | 1994 | P910066      |
| Spinal-Stim                                     | <ul style="list-style-type: none"> <li>Indicated as a spinal fusion adjunct to increase the probability of fusion success and as a nonoperative treatment for salvage of failed spinal fusion, where a minimum of nine months has elapsed since last surgery.</li> </ul>       | Orthofix         | 1996 | P850007/S027 |
| Cervical-Stim Model 505L Cervical Fusion System | <ul style="list-style-type: none"> <li>Indicated as an adjunct to cervical fusion surgery in patients at high risk for non-fusion</li> <li>A pulsed electromagnetic field system, was approved as an adjunct to cervical fusion surgery in</li> </ul>                          | Orthofix         | 2004 | P030034      |

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|                                                              |                                                                                                                                                              |                                  |      |         |
|--------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------|------|---------|
|                                                              | patients at high-risk for nonfusion.                                                                                                                         |                                  |      |         |
| ActaStim-S Spine Fusion Stimulator                           | <ul style="list-style-type: none"> <li>Indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels</li> </ul> | Theragen, Inc.                   | 2020 | P190030 |
| Xstim Spine Fusion Stimulator                                | <ul style="list-style-type: none"> <li>Indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels</li> </ul> | Xstim                            | 2024 | P230025 |
| <b><i>Implantable Electrical Bone Growth Stimulators</i></b> |                                                                                                                                                              |                                  |      |         |
| OsteoStim                                                    | <ul style="list-style-type: none"> <li>OsteoStim® (Electro-Biology), which may also be marketed under the trade name SPF (Biomet) was approved</li> </ul>    | EBI, LLC (now Highridge Medical) | 1980 | P79000  |
| SpF Implantable Spinal Fusion Stimulator                     | <ul style="list-style-type: none"> <li>Indicated as a spinal fusion adjunct to increase the probability of fusion success</li> </ul>                         | EBI, LLC (now Highridge Medical) | 1987 | P850035 |

### RATIONALE

#### 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 randomized controlled trials (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.

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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.

### DEFINITIONS

NA

### DISCLAIMER

*Capital Blue Cross' medical policies are used to determine coverage for specific medical technologies, procedures, equipment, and services. These medical policies do not constitute medical advice and are subject to change as permitted by law or applicable clinical evidence from independent treatment guidelines. Treating providers are solely responsible for medical advice and treatment of members. These policies are not a guarantee of coverage or payment. Payment of claims is subject to a determination regarding the member's benefit program and eligibility on the date of service, and a determination that the services are medically necessary and appropriate. Final processing of a claim is based upon the terms of contract that applies to the members' benefit program, including benefit limitations and exclusions. If a provider or a member has a question concerning this medical policy, please contact Capital Blue Cross' Provider Services or Member Services.*

### CODING INFORMATION

**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.

**Investigational for the following services:**

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- Semi-invasive electrical bone growth stimulation as an adjunct to lumbar spinal fusion surgery and for failed lumbar fusion.
- Invasive, semi-invasive, and noninvasive electrical bone growth stimulation as an adjunct to cervical fusion surgery and for failed cervical spine fusion.

| 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           |

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| <b>ICD-10-CM Diagnosis Codes</b> | <b>Description</b>                                                                                                     |
|----------------------------------|------------------------------------------------------------------------------------------------------------------------|
| 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                                   |
| 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:

| <b>Procedure Codes</b> |       |  |  |  |  |  |  |
|------------------------|-------|--|--|--|--|--|--|
| E0748                  | 20974 |  |  |  |  |  |  |

| <b>ICD-10-CM Diagnosis Codes</b> | <b>Description</b>                                                                                     |
|----------------------------------|--------------------------------------------------------------------------------------------------------|
| 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              |

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

### REFERENCES

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## POLICY HISTORY

|                 |                                                                                                                                                                                                                                                                                         |
|-----------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>MP 1.150</b> | <b>03/19/2020 Consensus Review.</b> Policy statement unchanged. References reviewed. Coding and Background updated.                                                                                                                                                                     |
|                 | <b>06/08/2021 Minor Review.</b> 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. |
|                 | <b>03/31/2022 Consensus Review.</b> No changes to policy statement. FEP updated. Coding and references reviewed.                                                                                                                                                                        |
|                 | <b>06/21/2023 Consensus Review.</b> No change to policy statement. Regulatory status updated. References updated. References and coding reviewed. No coding changes.                                                                                                                    |
|                 | <b>04/24/2024 Consensus Review.</b> No change to policy statement. References updated. Coding reviewed with no coding changes.                                                                                                                                                          |

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|  | <b>08/16/2024 Administrative Update.</b> 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 10/01/2024. |
|  | <b>04/02/2025 Minor Review.</b> Removed immunocompromised status and osteoporosis from MN criteria. Removed thoracic spinal fusion language. Background and References updated. No coding changes.                       |
|  | <b>07/10/2025 Administrative Update.</b> Removed Benefit Variations Section and updated Disclaimer.                                                                                                                      |
|  | <b>04/17/2026 Consensus Review.</b> No changes to policy statement. Updated policy formatting, cross-references, product variations, background, rationale, disclaimer, and references. No coding changes.               |

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